

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK**

CITY OF SYRACUSE, NEW YORK,

Plaintiff,

vs.

Civil Action

No. 5:18-cv-1184 (GTS/DEP)

**COMPLAINT AND
JURY DEMAND**

**PURDUE PHARMA, L.P.; PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
CEPHALON, INC.; TEVA PHARMACEUTICAL
INDUSTRIES, LTD.; TEVA PHARMACEUTICALS
USA, INC.; JOHNSON & JOHNSON; JANSSEN
PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA,
INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
DEPOMED, INC. n/k/a ASSERTIO THERAPEUTICS, INC.;
ENDO HEALTH SOLUTIONS, INC.; ENDO
PHARMACEUTICALS, INC.; ENDO GENERICS HOLDING,
INC.; PAR PHARMACEUTICAL COMPANIES, INC. n/k/a
ENDO GENERICS HOLDING, INC.; PAR PHARMACEUTICAL,
INC.; MALLINCKRODT PLC.; MALLINCKRODT, LLC.;
SPECGX, LLC.; MALLINCKRODT BRAND PHARMACEUTICALS,
INC.; MALLINCKRODT ENTERPRISES, LLC.; MALLINCKRODT
ENTERPRISES HOLDINGS, INC.; ALLERGAN PLC. f/k/a
ACTAVIS, PLC.; ALLERGAN FINANCE, LLC. f/k/a ACTAVIS, INC.
f/k/a WATSON PHARMACEUTICALS, INC.; WATSON
LABORATORIES, INC.; ACTAVIS, LLC.; ACTAVIS PHARMA, INC.
f/k/a WATSON PHARMA, INC.; INSYS THERAPEUTICS, INC.;
AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL
HEALTH, INC.; MCKESSON CORPORATION; H.D. SMITH, LLC.
f/k/a H.D. SMITH WHOLESALE DRUG COMPANY; ANDA, INC.;
RITE AID CORPORATION OF NEW YORK, INC.; RITE AID
OF MARYLAND, INC. d/b/a RITE AID MID-ATLANTIC CUSTOMER
SUPPORT CENTER, INC.; KPH HEALTHCARE SERVICES, INC.;
WALMART, INC. F/K/A WAL-MART STORES, INC.; JOHN DOE;
JOHN DOES; JOHN DOE CORPORATION, being a fictitious name(s)
used to designate a person, persons, partnership, sole proprietorship,
corporation or other entity responsible for developing, marketing,
distributing and/or selling prescription opioid drugs,**

Defendants.

TABLE OF CONTENTS TO COMPLAINT

	Page
Introduction.....	2
Parties.....	17
I. Plaintiff.....	17
II. Defendants.....	19
A. Manufacturer Defendants.....	19
1. Purdue Entities.....	19
2. Cephalon Entities.....	21
3. Janssen Entities.....	24
4. Depomed, Inc.....	27
5. Endo Entities.....	29
6. Mallinckrodt Entities.....	33
7. Actavis Entities.....	36
8. Insys Therapeutics, Inc.	38
B. Distributor Defendants.....	40
1. Amerisourcebergen Drug Corporation	40
2. Cardinal Health, Inc.....	41
3. McKesson Corporation	42
4. H.D. Smith, LLC.....	43
5. Anda, Inc.....	43
6. Rite Aid.....	44
7. KPH Health Services, Inc.	45
8. WalMart, Inc.	45
C. Doe Entities.....	45
D. Agency and Authority.....	46
Jurisdiction and Venue.....	46
Jury Demand	47
Factual Allegations	47
I. Opioids Are Addictive.....	47
II. No Scientific Evidence Supports Long Term Use of Opioids	50

III.	Defendants’ Schemes to Realize Blockbuster Profits.....	51
IV.	Defendants’ Schemes Expanded the Unsafe and Unapproved “Black Market” for the Opioid Drugs.....	56
V.	Manufacturer Defendants Use “Unbranded” Marketing to Evade Laws and Regulations.....	57
A.	Manufacturer Defendants KOLs	63
B.	Manufacturer Defendants' Corrupt Scientific Literature	65
C.	Manufacturer Defendants' Misuse of Treatment Guidelines	68
	1. FSMB	68
	2. AAPM/APS Guidelines	69
	3. American Geriatrics Society	71
	4. Guidelines Not Supported by Manufacturer Defendants	72
D.	Manufacturer Defendants' Misuse of CMEs.....	73
E.	Manufacturer Defendants' Misuse of Patient Education Materials and Front Groups	75
	1. American Pain Foundation	78
	2. The American Academy of Pain Medicine.....	80
F.	Defendants' Target Valuable and Lucrative Populations.....	81
	1. The Elderly.....	81
	2. Veterans	82
VI.	Manufacturer Defendants acted through and with the same network of Front Groups in the Creation, Promotion and Control of Unbranded Marketing	84
VII.	Manufacturer Defendants' Misrepresentations	85
A.	Manufacturer Defendants Misrepresented How Opioids Lead to Addiction.....	87
B.	Manufacturer Defendants Misrepresent That Opioids Improve Function.....	95

C.	Manufacturer Defendants Misrepresent That Addiction Risk Can Be Effectively Managed.....	100
D.	Manufacture Defendants Mislead With Use of Purportedly Scientific Terms Like "Pseudoaddiction"	106
E.	Manufacturer Defendants Claim Withdrawal Is Easily Managed.....	110
F.	Manufacturer Defendants Misrepresent Increased Doses Pose No Significant Additional Risks	113
G.	Manufacturer Defendants Deceptively Omit or Minimize The Effects Of Opioids And Overstate Risks Of Alternative Forms of Pain Treatment	117
VIII.	Manufacturer Defendants Engaged in Deceptive Marketing and Promoting, Both Branded and Unbranded Drugs, that Targeted and Reached New York State and City of Syracuse Prescribers.....	123
A.	Purdue	124
1.	Purdue's Deceptive Direct Marketing	125
2.	Purdue's Deceptive Third-Party Statements	131
a.	APF	131
i.	Purdue's Control of APF	131
ii.	<i>A Policymaker's Guide</i>	137
iii.	<i>Treatment Options: A Guide for People Living with Pain</i>	139
iv.	<i>Exit Wounds</i>	140
b.	Purdue's Work with Other Third-Party Front Group's and KOLs	140
i.	FSMB – Responsible Opioid Prescribing	140
ii.	AGS – Pharmacological Management of Pain in Older Persons	141
iii.	Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, And Improving Outcomes.....	142
iv.	Managing Patient's Opioid Use: Balancing the Need and Risk.....	142
v.	Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse	143
vi.	Overview of Management Options.....	143
c.	Purdue's Misleading Science	144

3.	Purdue's Deceptive Statements to New York State and City of Syracuse Prescribers and Patients.....	145
B.	Cephalon	148
1.	Cephalon's Deceptive Direct Marketing	149
a.	Cephalon's Fraudulent Off-Label Marketing of Actiq and Fentora	150
i.	Cephalon launched its fraudulent marketing scheme for Actiq.....	150
ii.	Cephalon fraudulently marketed Actiq's successor drug, Fentora – October 1, 2006.....	152
iii.	Reports of death and serious side effects led the FDA to issue a public health warning for Fentora – September 2007	154
iv.	The FDA rejected Cephalon's request for expanded approval of Fentora – May 6, 2008	155
v.	The FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") warned CEPHALON About its misleading advertising of Fentora–March 26, 2009.....	156
vi.	Cephalon continues to knowingly, deceptively, and illegally promote Fentora for off-label uses	157
b.	Cephalon's Misrepresentation of the Risks Associated with the Use of Opioids for the Long-Term Treatment of Chronic Pain	158
2.	Cephalon's Deceptive Third-Party Statements	160
a.	FSMB – Responsible Opioid Prescribing	161
b.	APF – <i>Treatment Options: A Guide for People Living with Pain</i>	162
c.	Key Opinion Leaders and Misleading Science	164

d.	Misleading Continuing Medical Education	165
3.	Cephalon's Deceptive Statements to New York State and City of Syracuse Prescribers and Patients.....	169
C.	Janssen.....	170
1.	Janssen's Deceptive Direct Marketing	171
a.	Janssen's Deceptive Sales Training	171
b.	Janssen's Deceptive Speakers Bureau Programs	175
c.	Janssen's Deceptive Unbranded Advertising.....	176
2.	Janssen's Deceptive Third-Party Statements.....	177
a.	AAPM and AGS – <i>Finding Relief: Management for Older Adults</i>	177
b.	AGS – Misleading Medical Education	181
c.	APF	181
i.	<i>Let's Talk Pain</i>	182
ii.	<i>Exit Wounds</i>	185
3.	Janssen's Deceptive Statements to New York State and City of Syracuse Prescribers and Patients.....	185
a.	Janssen's Deceptive Medical Education Programs in New York State.....	186
b.	Janssen's Deceptive Detailing Practices in New York State.....	186
D.	Depomed	187
1.	Depomed's Deceptive Direct Marketing.....	188
a.	Depomed's Deceptive Sales Training.....	189
b.	Depomed's Deceptive Speakers Bureau Programs.....	191
c.	Depomed's Advertisements Contain Misleading Safety Messages.....	193

d.	Depomed's Deceptive Unbranded Advertising.....	193
2.	Depomed's Deceptive Third Party Statements.....	194
3.	Depomed's Deceptive Statements to New York State and City of Syracuse Prescribers and Patients	197
a.	Depomed's Deceptive Medical Education in New York State.....	197
b.	Depomed's Deceptive Practices in New York State.....	197
i.	Depomed Sales Representatives Promoted Lazanda for Unsafe and Unapproved Uses.....	198
ii.	Depomed Sales Representatives Promoted Nucynta and Nucynta ER For Unsafe and Unapproved Uses.....	199
E.	Endo.....	203
1.	Endo's Deceptive Direct Marketing.....	203
a.	Endo's Sales Force and Deceptive Sales Training.....	204
i.	Endo's Sales Force Deceptively Minimized the Risks of Addiction Associated with Chronic Opioid Therapy.....	207
ii.	Endo's Sales Force Deceptively Implied that Chronic Opioid Therapy Would Improve Patient's Ability to Function.....	209
iii.	Endo's Sales Force Deceptively Presented the Risks and Benefits of Opioids To Make Them Appear Safer Than Other Analgesics.....	211
b.	Endo's Speakers' Bureau Programs Deceptively Minimized the Risks of Addiction Associated with Chronic Opioid Therapy.....	211

c.	Endo's Misleading Journal Supplement.....	213
d.	Endo's Deceptive Unbranded Marketing.....	214
2.	Endo's Deceptive Third-Party Statements.....	214
a.	APF.....	215
i.	Misleading Medical Education.....	219
ii.	<i>Painknowledge.com</i>	221
iii.	<i>Exit Wounds</i>	222
b.	Other Front Groups: FSMB, AAPM, and AGS.....	223
c.	Key Opinion Leaders and Misleading Science.....	225
3.	Endo's Deceptive Statements to New York and City of Syracuse Prescribers and Patients.....	228
F.	Mallinckrodt.....	232
1.	Mallinckrodt's Deceptive Marketing.....	233
G.	Actavis.....	234
1.	Actavis' Deceptive Direct Marketing.....	235
a.	Actavis' Deceptive Sales Training.....	237
b.	Actavis' Deceptive Speaker Training.....	241
2.	Actavis' Deceptive Statements Reached New York State and City of Syracuse Prescribers and Patients.....	243
IX.	Insys Therapeutics and the Systematic Manipulation of Prior Authorization.....	244
A.	Insys "Off Label" Marketing Campaign.....	246
X.	Manufacturer Defendants Knew Their Marketing Was False, Unfounded, Dangerous, and Would Harm Plaintiffs.....	257

XI.	Manufacturer Defendants Fraudulently Concealed Their Misrepresentations.....	257
XII.	Manufacturer Defendants False Representations to Managed Care Plans	259
A.	Background Regarding Third Party Payors and Prescription Drug Coverage.....	261
B.	Formulary Access and Coverage Enterprises/Schemes	267
1.	Purdue’s False and Misleading Messages To Third Party Payors.....	267
2.	Cephalon’s False and Misleading Messages To Third Party Payors.....	270
3.	Janssen’s False and Misleading Messages To Third Party Payors.....	273
4.	Depomed’s False and Misleading Messages To Third Party Payors.....	275
5.	Endo’s False and Misleading Messages To Third Party Payors.....	275
6.	Mallinckrodt’s False and Misleading Messages To Third Party Payors.....	277
7.	Actavis’ False and Misleading Messages To Third Party Payors.....	277
8.	Insys’s False and Misleading Messages To Third Party Payors.....	278
C.	Concerted Efforts of All Defendants to Suppress Evidence of Diversion.....	286
XIII.	Distributor Defendants Have A Duty to Report and Stop Suspicious Orders of Opioids	287
A.	Distributor Defendants’ Duties.....	287
B.	The ARCOS Database.....	293
XIV.	Distributor Defendants Breached Their Duties and the DEA Gets Involved.....	294
A.	The DEA Sent Letters to the Distributor Defendants.....	294
B.	DEA Actions against the Distributor Defendants.....	296
C.	Distributor Defendants Misled the Public Concerning their Duties and Compliance.....	303

D.	Distributor Defendants Breached their Duties.....	308
XV.	The Manufacturer Defendants also Failed to Prevent Diversion and Monitor, Report, and Stop Suspicious Orders.....	310
XVI.	Defendants' Conduct and Breaches of Duties Caused the Plaintiff Harm.....	315
XVII.	Defendants' Opioid Marketing and Diversion in New York State and City of Syracuse.....	318
A.	The Results Of Defendants' Wrongful Conduct On New York And City of Syracuse.....	319
1.	New York and City of Syracuse are Flooded with Prescription Opioids as a Result of Defendants' Conduct.....	319
2.	Opioids are Killing New Yorkers.....	327
a.	Prescription Opioid Abuse and its Effect on New York and City of Syracuse.....	327
b.	Impact on Services Offered by New York, Onondaga County and City of Syracuse	334
i.	Health Care Costs.....	334
ii.	Opioid Related Emergency Calls/ Emergency Department Visits.....	334
iii.	Opioid-Related Hospital Admissions/ Discharges.....	336
iv.	Overdose Deaths.....	338
v.	Increase in Costs for Law Enforcement and Training and Naloxone.....	341
vi.	Syracuse Fire Department.....	344
vii.	Increase in Drug Related Autopsies at the Onondaga County Medical Examiner's Office.....	345
viii.	Babies born with Neonatal Abstinence Syndrome/Health Related/Foster Care Costs.....	346
ix.	Opioid Treatment Centers.....	356
x.	Onondaga County Sharps, Needles and Drug Disposal (SNADD) Programs.....	361

Tolling And Fraudulent Concealment.....	362
Count I: Public Nuisance (Against All Defendants).....	365
Count II: Racketeer Influenced And Corrupt Organizations Act, 18 U.S.C. § 1961, Et Seq. (Against All Defendants).....	367
A. The Opioid Diversion Enterprise.....	370
B. Conduct of the Opioid Diversion Enterprise.....	381
C. Pattern of Racketeering Activity.....	385
1. The RICO Defendants Engaged in Mail and Wire Fraud	386
2. The RICO Defendants Manufactured, Sold, and/or Dealt in Controlled Substances and Their Crimes Are Punishable as Felonies.....	394
D. Damages.....	399
Count III: Racketeer Influenced And Corrupt Organizations Act, 18 U.S.C. § 1962(D), Et. Seq. (Against All Defendants).....	400
A. The Opioid Diversion Enterprise.....	400
B. Conduct of the Opioid Diversion Enterprise.....	400
C. Pattern of Racketeering Activity.....	400
D. Damages.....	401
Count IV: Negligence (Against All Defendants).....	401
Count V: Unjust Enrichment (Against All Defendants).....	403
Count VI: Common Law Fraud (Against All Defendants).....	404
Count VII: Damages Resulting From Civil Conspiracy (Against All Defendants).....	426
Count VIII: Deceptive Acts And Practices – New York General Business Law § 349 (Against All Defendants).....	427
Count IX: False Advertising – New York General Business Law § 350 (Against All Defendants).....	427

Count X: Violation Of New York Social Services Law § 145-B (Against All Defendants).....	428
Claim For Relief.....	428

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK**

-----X
City of Syracuse, New York

Plaintiff,

v.

Purdue Pharma, L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Cephalon, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Depomed, Inc. n/k/a Assertio Therapeutics, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Endo Generics Holding, Inc.; Par Pharmaceutical Companies, Inc. n/k/a Endo Generics Holding, Inc.; Par Pharmaceutical, Inc.; Mallinckrodt Plc.; Mallinckrodt, LLC.; Specgx, LLC.; Mallinckrodt Brand Pharmaceuticals, Inc.; Mallinckrodt Enterprises, LLC.; Mallinckrodt Enterprises Holdings, Inc.; Allergan Plc. f/k/a Actavis, Plc.; Allergan Finance, LLC. f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis, LLC.; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Insys Therapeutics, Inc.; AmerisourceBergen Drug Corporation; Cardinal Health, Inc.; McKesson Corporation; H.D. Smith, LLC. f/k/a H.D. Smith Wholesale Drug Company; Anda, Inc.; Rite Aid Corporation of New York, Inc.; Rite Aid of Maryland, Inc. d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc.; KPH Healthcare Services, Inc.; Walmart, Inc. f/k/a Wal-Mart Stores, Inc.; John Doe; John Does; John Doe Corporation, being a fictitious name(s) used to designate a person, persons, partnership, sole proprietorship, corporation or other entity responsible for developing, marketing, distributing and/or selling prescription opioid drugs,

Defendants.
-----X

Civil Action

No.

**COMPLAINT AND JURY
DEMAND**

Plaintiff, City of Syracuse, by its attorneys, Cherundolo Law Firm, PLLC, Brindisi, Murad, Brindisi & Pearlman, LLP, and Robert F. Julian, P.C. complaining of the Defendants, respectfully alleges, upon information and belief, as follows:

INTRODUCTION

1. Plaintiff spends a significant amount of dollars each year to provide or pay for health care, pharmaceutical care, and other necessary services and programs on behalf of eligible employees and retirees, including payments for prescription opium-like painkillers ("opioids"), which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants.

2. Plaintiff also provides a wide range of other services on behalf of its residents, including law enforcement services and emergency medical response services by the police department and fire department, and other services for families and children in the City of Syracuse.

3. Plaintiff has their offices located at 223 E. Washington Street, Syracuse City Hall, Syracuse, New York, 13202 and employs approximately 2,327 people in 23 different departments. Plaintiff funds its own prescription drug benefit plan for the benefit of its full-time employees, certain retirees and dependents, through which it pays those employees' or retirees or dependents' cost of prescription drugs, including opioids.

4. Ninety-one Americans die a day from opioid overdoses, which includes prescription opioids and heroin.¹ Deaths from prescription opioids—drugs like oxycodone, hydrocodone, and methadone—have more than quadrupled since 1999 and more than 6 million suffer from prescription drug abuse disorders.² “This is a very real epidemic - and warrants a strong public

¹ CDC, *Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic*, August 30, 2017, Web 8 Dec. 2017.

² CDC. *Wide-ranging online data for epidemiologic research (WONDER)*. Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at <http://wonder.cdc.gov>

health response,” states Andrea Gielen, ScD, Director of the Johns Hopkins Center for Injury Research and Policy.

5. Drug companies should never place their desire for profits above the health and well-being of their customers or their communities. Defendants know prescribing doctors and other health-care providers rely on drug companies' statements in making treatment decisions, and, as such, drug companies must tell the truth when marketing their drugs and ensure that their marketing claims are supported by science and medical evidence.

6. Defendants broke these simple rules and unleashed a healthcare crisis with far-reaching financial, social, and deadly consequences across the nation, in New York State and in City of Syracuse.

7. Defendants manufacture, market, and sell prescription opioids (hereinafter "opioids"), which are powerful narcotic painkillers.

8. Opioids include brand-name drugs like OxyContin and generics like oxycodone and hydrocodone. They are derived from or possess properties similar to opium and heroin, they are highly addictive and dangerous, and are regulated by the United States Food and Drug Administration (“FDA”) and under the Controlled Substances Act (“CSA”) as Schedule II controlled substances. Substances in this schedule have a high potential for abuse, which may lead to severe psychological or physical dependence, and are dangerous.

9. Historically, opioid drugs were considered too addictive and debilitating for the treatment of chronic pain, such as back pain, migraines and arthritis (hereinafter, "chronic pain" means non-cancer pain lasting three months or longer), and were only used to treat short-term acute pain or for palliative (end-of-life) care.

10. However, by the late 1990s, and continuing today, Defendants began or

participated in a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, thereby creating a far broader group of patients more likely to become addicted and suffer other adverse effects from long-term use. As part of this scheme, Defendants spent, and continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

11. As to the risks, Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no "good evidence" to support Defendants' claims.

12. Defendants' false and misleading messages were for the purpose of reversing the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians that Defendants recruited for their support of their marketing messages. Borrowing a page from Big Tobacco's playbook, Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs" or "Paid Consultant Doctors") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (hereinafter, "Front Groups"). Defendants then

worked together with those Paid Consultant Doctors and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and Paid Consultant Doctors, Defendants persuaded doctors and patients that what they had long known - that opioids are addictive drugs, unsafe in most circumstances for long-term use - was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

13. Addiction is a spectrum of substance use disorders ("SUDs") that range from misuse and abuse of drugs to addiction.³ Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

14. Defendants knew that, barring exceptional circumstances, opioids are too addictive and too debilitating for long-term use for chronic pain.

15. Defendants knew that, with prolonged use, the effectiveness of opioids wanes, requiring increases in doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction⁴

16. Defendants knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (*i.e.*, not longer than 90 days) in managed settings (*e.g.*, hospitals) where the risk of addiction and other adverse outcomes were significantly minimized.

17. Each Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the

³ *Diagnostic and Statistical Manual of Mental Disorders* (5th ed. 2013) ("DSM-V").

⁴ See, *e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status, 1 Progress in Pain Res. & Mgmt.*, 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994).

falsity of each Defendant's misrepresentations has been confirmed by the FDA and the Centers for Disease Control and Prevention ("CDC"), including in the CDC's *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016, and approved by the FDA ("2016 CDC Guideline").

18. Opioid manufacturers, including Defendants ENDO Pharmaceuticals, Inc., and Purdue Pharma, L.P., have entered into settlements agreements with public entities which prohibit these companies from making many of the misrepresentations identified in this Complaint in other jurisdictions. Yet even now, each Defendant continues to misrepresent the risks and benefits of long-term opioid use in New York and continues to fail to correct its past misrepresentations. Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs; they generated \$11 billion in revenue for drug companies in 2014 alone.

19. In an open letter to the nation's physicians in August 2016, the then U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors ... [m]any of [whom] were even taught - incorrectly - that opioids are not addictive when prescribed for legitimate pain."⁵ Surgeon General Murthy stated, "*Nearly two decades ago, we were encouraged to be more aggressive about treating pain, often without enough training and support to do so safely. This coincided with heavy marketing of opioids to doctors. Many of us were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain. The results have been devastating. Since 1999, opioid overdose deaths have quadrupled and opioid prescriptions have increased markedly – almost enough for every adult in America to have a bottle of pills. Yet the amount of pain reported by Americans has not changed. Now, nearly two million people in America have a prescription opioid use disorder, contributing to increased heroin use and the*

⁵ Vivek H. Murthy, *Letter from the Surgeon General, August 2016 (emphasis added)*

*spread of HIV and hepatitis C.”*⁶ Surgeon General Murthy asked our nations doctors to make a commitment to turn the tide on the opioid crisis by taking the pledge at *www.TurnTheTideRx.org*. Murthy, in an attempt to build a national movement of clinicians, asked three things: (1) to educate ourselves to treat pain safely and effectively; (2) to screen our patients for opioid use disorder and provide or connect them with evidence-based treatment; and (3) to help shape how the rest of the country sees addiction by talking about and treating it as a “chronic illness, not a moral failing”.⁷

20. This epidemic, fueled by opioids lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

21. To date, there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.

22. Despite the foregoing knowledge, in order to expand the market for opioids and realize blockbuster profits, Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public that would encourage the use of opioids for longer periods of time and to treat a wider range of problems, including such common aches and pains as lower back pain, arthritis, and headaches.

23. Manufacturer Defendants, individually and collectively, accomplished that false perception through a coordinated, sophisticated, and highly deceptive marketing campaign that began in the late 1990s, which became more aggressive and continues today.

24. Manufacturer Defendants, individually and collectively, accomplished their

⁶ *Id.*

⁷ *Id.*

marketing campaign goal by convincing doctors, patients, and others that the benefits of using opioids to treat chronic pain outweighed the risks, and that opioids could be safely used by most patients.

25. Manufacturer Defendants, individually and collectively, knowing that long-term opioid use causes addiction, misrepresented the dangers of long-term opioid use to physicians, pharmacists, and patients by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

26. Defendants' marketing campaign has been extremely successful in expanding opioid use. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled.⁸ In 2010, 254 million prescriptions for opioids were filled in the U.S. – enough to medicate every adult in America around the clock for a month.⁹ In that year, 20% of all doctors' visits resulted in the prescription of an opioid (nearly double the rate in 2000).¹⁰ While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.¹¹ By 2014, nearly two million Americans either abused or were dependent on opioids.¹²

27. Defendants' campaign has been extremely profitable for them. In 2012 alone,

⁸ CDC, *Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic*. Available at: <http://www.cdc.gov/drugoverdose/epidemic/index.html> (accessed January 9, 2017) (internal footnotes omitted).

⁹ *Fortune Magazine*, "Oxycontin: Purdue Pharma's Painful Medicine, November 9, 2017, Web 8 Dec 2017, which stated,

"254 million prescriptions for opioids were filled in the U.S., according to Wall Street analysts Cowen & Co. Enough painkillers were prescribed to "medicate every American adult around the clock for a month," the federal Centers for Disease Control reported on Nov. 1."

¹⁰ Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) *Med. Care* 870-78 (2013).

¹¹ Manchikanti, et al., *Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten- Year Perspective*, 13 *Pain Physician* 401-435 (2010).

¹² CDC, *Injury Prevention & Control: Opioid Overdose, Prescription Opioids*. Available at: <http://www.cdc.gov/drugoverdose/opioids/prescribed.html> (accessed January 9, 2017).

opioids generated \$8 billion in revenue for drug companies.¹³ Of that amount, \$3.1 billion went to PURDUE for its OxyContin sales.¹⁴ Purdue Pharma is 100% owned by the Sackler Family, the 16th richest family in America with a \$14 billion net worth, who made their fortune on Oxycontin.¹⁵

28. Defendants' marketing campaign has been extremely harmful to Americans. Overdoses from prescription pain relievers are a driving factor in a 15-year increase in opioid overdose deaths. From 2000 to 2014 nearly half a million people died from such overdoses.¹⁶

29. In 2012, an estimated 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.¹⁷ Between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.¹⁸

30. Opioid addiction and overdose have reached epidemic levels over the past decade. On March 22, 2016, the FDA recognized opioid abuse as a "*public health crisis*" that has a "*profound impact on individuals, families and communities across our country.*"¹⁹ (emphasis added).

31. "Prescription opioids, heroin, and synthetic opioid drugs all work through the

13 B. Meier & B. Marsh, *The Soaring Cost of the Opioid Economy*, N.Y. Times (June 22, 2013).

14 K. Eban, *Purdue Pharma's Painful Medicine*, Fortune Magazine (Nov. 9, 2011).

15 Morrell, Alex, "The OxyContin Clan: The \$14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families," *Forbes.com*, 1 July 2015. Web. 10 Oct. 2017; and Ryan, Harriet, et al., "'You want a Description of Hell?' Oxycontin's 12-Hour Problem," *The Los Angeles Times*, 5 May 2016. Web. 25 Oct. 2017.

16 CDC, *Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic*, *supra*.

17 Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

18 J. Boscarino et al., *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) *Addiction* 1776 (2010); J. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30(3) *Journal of Addictive Diseases* 185 (2011).

19 FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm> (accessed January 9, 2017).

same mechanism of action.”²⁰ The National Institute on Drug Abuse states that “[p]rescription opioid pain medicines such as OxyContin® and Vicodin® have effects similar to heroin. Research suggests that misuse of these drugs may open the door to heroin use. Nearly 80 percent of Americans using heroin (including those in treatment) reported misusing prescription opioids first.”²¹

32. “The emergence of illicitly manufactured synthetic opioids including fentanyl, carfentanil, and their analogues represents an escalation of the ongoing opioid overdose epidemic.”²²

33. Defendants’ marketing campaign has failed to achieve any material health care benefits since there has been no overall change in the amount of pain that Americans report since 1999.²³

34. The National Institutes of Health (“NIH”) not only recognizes the opioid abuse problem, but also identifies Defendants’ “aggressive marketing” as a major cause. “Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies.*”²⁴ As shown below, the “drastic increases in the number of prescriptions written and dispensed” and the “greater social acceptability for using medications for different purposes” are the direct result of “the aggressive marketing by pharmaceutical companies.”

35. To regulate highly addictive drugs, like opioids, in 1970, Congress devised a

20 Compton, Wilson M. M.D., “Research on the Use and Misuse of Fentanyl and Other Synthetic Opioids,” National Institute on Drug Abuse, 30 June 2017. Web. 24 Oct. 2017.

21 What is heroin? National Institute on Drug Abuse, Revised, July 2017. Web 24 Oct. 2017.

22 Compton, Wilson M. M.D., “Research on the Use and Misuse of Fentanyl and Other Synthetic Opioids,” National Institute on Drug Abuse, 30 June 2017. Web. 24 Oct. 2017.

23 CDC, *Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic*, *supra*.

24 America’s Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed January 9, 2017) (*emphasis added*).

“closed” chain of distribution specifically designed to prevent the diversion of legally produced controlled substances into the illicit market. This closed system imposes duties on the Distributor Defendants and Manufacturer Defendants to monitor, identify, halt, and report “suspicious orders” of controlled substances.²⁵

36. Distributor Defendants control 85% of the market share for distributing prescription opioids. Distributor Defendants are Fortune 500 corporations on the New York Stock Exchange engaged in the nationwide wholesale distribution of prescription drugs.²⁶

37. Data that reveals the specific amount of opioids Distributor Defendants distributed in New York State and City of Syracuse is hidden from public view in the U.S Drug Enforcement Administration’s (DEA) confidential Automation of Reports and Consolidated Orders System (ARCOS) database.²⁷ Neither the DEA²⁸ nor the Distributor Defendants²⁹ will voluntarily disclose the data necessary to identify with specificity those transactions.

38. Based on the data publicly available, Distributor Defendants failed to identify, report, and stop obviously suspicious orders, flooding the market with opioid prescriptions in New York State and City of Syracuse. As previously indicated within the past two decades, the amount of

²⁵ See 21 C.F.R. § 1301.74; *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

²⁶ See *Fed. Trade Comm’n v. CARDINAL HEALTH, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998).

²⁷ See *Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015).

²⁸ See Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit (“SARF”), FOI, Records Management Section (“SAR”), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ) (filed in *Madel v. USDOJ*, Case No. 0:13-cv-02832-PAM-FLN, Doc. 23, ¶ 40 (D. Minn. Feb. 6, 2014) (noting that “the data is kept confidential by the DEA. . .”).

²⁹ See Declaration of Tina Lantz, CARDINAL HEALTH VP of Sales Operation, (filed in *Madel v. USDOJ*, Case No. 0:13-cv-02832-PAM-FLN, Doc. 93, ¶ 6 (D. Minn. Nov. 2, 2016) (“CARDINAL HEALTH does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. CARDINAL HEALTH relies on DEA to protect its confidential business information reported to the Agency.”).)

prescription opioids sold in the U.S. nearly quadrupled³⁰ and enough opioid prescriptions were filled in the United States to medicate every adult in America around the clock for a month.³¹

39. A West Virginia reporter obtained the confidential ARCOS data that Distributor Defendants refuse to release that revealed that “drug companies shipped nearly 9 million [opioid] pills over two years to one pharmacy in the town of Kermit, W. Va., population 392. The newspaper reported that drug wholesalers distributed 780 million pills of oxycodone and hydrocodone in the state over six years.”³² Those shipments amounted to 433 pain pills for every person in West Virginia.

40. Each Distributor Defendant has been investigated—and some fined—by the DEA for failing to report suspicious orders of opioids to the DEA. As recognized by a DEA supervisor, “The distributors are important. They’re like the quarterback. They distribute the ball.”³³

41. The rising numbers of persons addicted to opioids have led to significantly increased health care costs as well as a dramatic increase of social problems, including drug abuse and diversion³⁴ and the commission of criminal acts to obtain opioids throughout the United States, including New York State and City of Syracuse. Consequently, public health and safety throughout the United States, including City of Syracuse, has been significantly and negatively impacted due to the misrepresentations and omissions by Defendants regarding the appropriate uses and risks of opioids, ultimately leading to widespread inappropriate use of the drug.

42. Between 1996 and 2006, the New York State consumption of hydrocodone

30 “Understanding the Epidemic, Drug Overdose Deaths in the United States Continue to Increase in 2015,” Centers for Disease Control and Prevention. Web. 24 Oct. 2017.

31 *Fortune Magazine*, “Oxycontin: Purdue Pharma’s Painful Medicine,” *supra*.

32 Ornstein, Charles, “Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic,” *NPR.org*, 27 Jan. 2017. Web. 24 Oct. 2017.

33 *Id.*

34 According to the CDC, when prescription medicines are obtained or used illegally, it is called “drug diversion.”

increased from approximately 2,000 milligrams (mgs) per person to 12,000 mgs per person. Oxycodone consumption increased from approximately 1,000 mgs per person to 16,000 mgs per person, according to Dr. Andrew Kolodny, the Chief Medical Officer of Phoenix House, a nonprofit addiction treatment organization, and senior scientist at the Heller School for Social Policy and Management at Brandeis University, and Executive Director and co-founder of Physicians for Responsible Opioid Prescribing (PROP).³⁵ At the same time, health care admissions for opioid analgesic abuse has risen nationally and in New York State at rates of greater than 300%.

43. It is hardly necessary to say that in the United States, New York State, and the City of Syracuse, our citizens are now awash in opioids and engulfed in a public health crisis the likes of which have never been seen before. Between 2005 and 2014, the state documented a 115% increase in heroin treatment admissions in upstate New York. In all, approximately 1.4 million New Yorkers suffer from a substance abuse disorder.³⁶

44. The result of opioid crisis within the borders of the City of Syracuse has been catastrophic. Opioids have become the main source of unintentional drug overdose in the state and county. Due to the vast supply of opioids, the number of annual deaths attributable to unintentional drug overdoses has rapidly increased. During the last five years for which data are available on opioid use, misuse, morbidity, and mortality, both heroin and opioid analgesic-related deaths have increased.³⁷

45. In the County of Onondaga, where the City of Syracuse is located, in 2015, there

³⁵ *Adirondack Daily Enterprise, Leading Opioid Epidemic Expert Speaks to Experts in Lake Placid, Dec. 8, 2017; Web 8 Dec. 2017.*

³⁶ *A Primer on NY's Heroin Epidemic, New York State Association of Counties, July 2016.*

³⁷ *New York Opioid Poisoning, Overdose and Prevention, 2015 Report to the Governor and NYS Legislature, New York State Department of Health.*

were 307 outpatient emergency room visits for opioid-related overdoses,³⁸ and, in 2016, there were 484 outpatient emergency room visits for opioid-related overdoses³⁹, and, from January – September of 2017, there have been 220 outpatient emergency room visits for opioid-related overdoses.⁴⁰ In Onondaga County in 2015, there were 94 hospitalizations for opioid-related overdoses⁴¹, and, in 2016, there were 101 hospitalizations for opioid-related overdoses,⁴² and, from January - September of 2017 there were 66 hospitalizations for opioid-related overdoses.⁴³

46. Law Enforcement in Onondaga County, in which the City of Syracuse police department is located, has administered Naloxone, a medication used to block the effects of opioids, especially in overdose, 33 times through December 31, 2015,⁴⁴ with a staggering increase to 83 times through December 31, 2016, and 37 times through December, 2017;⁴⁵ and, in Onondaga County, where the City of Syracuse is located, EMS has administered Naloxone 548 times through December 31, 2015,⁴⁶ with an increase to 568 times through December 31, 2016, and 180 times through December 31, 2017.⁴⁷

47. In Onondaga County, where the City of Syracuse is located, there were 44 opioid overdose deaths in 2013, 59 opioid overdose deaths in 2014, 78 opioid overdose deaths in 2015, 124 opioid overdose deaths in 2016 and 58 opioid overdose deaths between January – September of 2017.⁴⁸ “The demographics of individuals who have died from an opioid-related overdose provide

38 New York State – County Opioid Quarterly Report, Published October, 2017.

39 New York State – County Opioid Quarterly Report, Published October, 2017.

40 New York State – County Opioid Quarterly Report, Published October, 2017 and April, 2018.

41 New York State – County Opioid Quarterly Report, Published October, 2017.

42 *Id.*

43 New York State – County Opioid Quarterly Report, Published October, 2017 and April, 2018.

44 New York State - County Opioid Quarterly Report, Published April, 2017.

45 New York State - County Opioid Quarterly Report, Published October, 2017 and April, 2018.

46 New York State - County Opioid Quarterly Report, Published April, 2017.

47 New York State - County Opioid Quarterly Report, Published October, 2017 and April, 2018.

48 See New York State – County Opioid Quarterly Report, Published April, 2017; and New York State – County Opioid Quarterly Report, Published October, 2017 and April, 2018.

insight into the populations most affected by opioid addiction in Onondaga County, were the City of Syracuse is located. In Onondaga County, where the City of Syracuse is located, men are more likely to die of an opioid overdose than women. From 2014-2016, 68.4% of unintended opioid-related deaths occurred among males while 31.6% occurred among females. The vast majority of recent (2014- 2016) opioid-related deaths have occurred among whites (86.0%), with 11.4% occurring among blacks. In Onondaga County, where the City of Syracuse is located, opioid-related deaths by age indicate that nearly one third (27.9%) of deaths between 2014 and 2016 were among individuals aged 30-39 years.⁴⁹

48. The commission of criminal acts to obtain opioids is an inevitable consequence of opioid addiction. Onondaga County, in which the City of Syracuse is located, has been designated by the federal government's Office of National Drug Control Policy as a "*High Intensity Drug trafficking Area*", which is a program designed to help local law enforcement agencies coordinate with federal Drug Enforcement Agencies to break up drug rings. According to Onondaga District Attorney William Fitzpatrick this program is helping to disrupt narcotic trafficking in Syracuse, a crossroads for two interstate highways that serve as major routed for drug dealers.⁵⁰

49. These alarming statistics do not fully illustrate the toll of prescription opioid abuse on patients and their families, as the dramatic increase in opioid prescriptions to treat chronic pain has resulted in a population of drug seeking addicts. Physicians' efforts to reverse course for chronic pain patients with long term opioid dependence are often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that are diverted to supply these patients.

⁴⁹ Onondaga Community Health and Improvement Plan,

<http://www.ongov.net/health/documents/OnondagaCountyCHA-CHIP.pdf>

⁵⁰ Trump axes drug-fighting program critical to Upstate NY, May 8, 2017 http://www.syracuse.com/politics/index.ssf/2017/05/schumer_trump_axes_drug-fighting_program_critical_to_upstate_ny.html

50. Prescription opioid abuse has not displaced heroin, but rather triggered resurgence in its use, imposing additional burdens on the Plaintiff, CITY OF SYRACUSE, and its agencies, that address heroin use and addiction. Individuals who are addicted to prescription opioids often transition to heroin because it is less expensive, readily available, and provides a similar high to the drugs to which they became addicted.

51. Plaintiff, CITY OF SYRACUSE'S, residents who suffer from chronic pain deserve both appropriate care and the ability to make decisions based on accurate and complete information about treatment risks and benefits. Defendants' deceptive marketing campaign has and continues to deprive Plaintiff, CITY OF SYRACUSE'S, residents and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

52. Defendants' conduct has also exacted, and foreseeably so, a financial burden on Plaintiff, CITY OF SYRACUSE, and its agencies have spent hundreds of thousands of dollars on opioid prescriptions for chronic pain.

53. To redress these violations of law, and the Defendants' reckless and wanton behavior and total disregard for the rights and well-being of the citizens of Plaintiff, CITY OF SYRACUSE, seeks damages for the amounts it has paid for excessive opioid prescriptions and in connection with the results of those prescriptions (*e.g.*, addiction treatment costs, law enforcement, etc.). Plaintiff also seeks punitive damages, treble damages, and attorneys' fees and costs, in addition to granting any other equitable relief authorized by law.

PARTIES

I. Plaintiff

54. The City of Syracuse, located in central New York State, is the County Seat for Onondaga County, New York, and has a population of approximately 145,170 people. It is the fifth most populous city in the state of New York, and is the most populous city in central New York. Syracuse is located at the intersection of Interstates 81 and 90, and its airport, Hancock International Airport, is the largest in the region. Other major interstates that run through the Syracuse area include Interstate 690, which runs east-west through the City and provides access to Interstate 90, as well as to Syracuse's northwestern and eastern suburbs; and Interstate 481 that forms an eastern loop around the city and continues to the northwest as NY 481 to Fulton and Oswego, on the shore of Lake Ontario.

55. Syracuse is home to Syracuse University, a major research university. Directly adjacent to Syracuse University is the State University of New York College of Environmental Science and Forestry – a doctoral degree granting institution. LeMoyne College is a nationally recognized Jesuit school on the city's eastern border. Onondaga Community College has its main campus in the adjacent Town of Onondaga and has two smaller campuses downtown and in the suburb of Liverpool. A branch of SUNY's Empire State College is located in downtown Syracuse, along with a campus of the nationwide Bryant & Stratton College. A campus of ITT Technical Institute also calls the Syracuse metropolitan area home, also located in Liverpool. There are also the Pomeroy College of Nursing at Crouse Hospital and St. Joseph's College of Nursing.

56. Also serving Syracuse is the Onondaga County Supreme and County Court, which is the trial court of general jurisdiction for Syracuse. It is also the administrative court for the Fifth District of the New York State Unified Court System. The U.S. District Court for the Northern

District of New York also holds court in downtown Syracuse at the James Hanley Federal Building.

57. The City of Syracuse also has major hospitals located within its boundaries, which include Upstate University Hospital, Upstate Golisano Children's Hospital, Upstate University Hospital - Community Campus, St. Joseph's Hospital Health Center and Crouse Hospital.

58. The City of Syracuse has its own police department, which covers a land area of 25.8 square miles. The Syracuse Police Department is the principal law enforcement agency for the City of Syracuse, and has its headquarters located in the John C. Dillon Public Safety Building at 511 South State Street, Syracuse, New York. As of December 31, 2017, there were 417 sworn officers and 68 civilian personnel employed by the Syracuse Police Department.⁵¹ The budget for fiscal year ending June 30, 2019 for the police department is \$48,038,599.

59. The City of Syracuse also has its own fire department located at 511 South State Street, 607 Public Safety Building Syracuse, New York 13202. The Syracuse Fire Department protects a 25-square-mile area with a population of 145,000 plus that grows significantly during daytime hours. The department provides fire protection and prevention services for four major hospitals, many downtown office buildings, Hancock International Airport, Interstates 81 and 690, as well as Syracuse University and the Carrier Dome. Currently over 350 firefighters staff the department and answer over 21,000 alarms a year of which over 1,000 are fires. In addition to fire protection and prevention services, the Syracuse Fire Department provides emergency medical services and technical rescue services. The fiscal year ending June 30, 2019 budget for the police department is \$33,601,910.

60. According to the 2014 estimates from the American Community Survey, the median income for a household in the city was \$31,566, and the median income for a family was

⁵¹ *Syracuse Police Department Annual Report 2017*. <http://www.syracusepolice.org/document/2515.pdf>.

\$38,794. Males had a median income of \$39,537 versus \$33,983 for females. The per capita income for the city was \$19,283. About 28.2% of families and 35.1% of the population were below the poverty line, including 50% of those under age 18 and 16.7% of those age 65 and over.

61. Plaintiff provides a wide range of services on behalf of its residents, including law enforcement, fire protection, emergency medical response, parks and recreation programming, code enforcement, and neighborhood and business development work. As mentioned above, Plaintiff also self-insures its own prescription drug benefits plan for approximately 4,143 employees and retirees. Plaintiff's health insurance plan for employees and retirees is also entirely self-funded.

62. Plaintiff brings this action on its own behalf and also as subrogee of its employees and residents and, as such, Plaintiff stands in the shoes of its subrogors, and is entitled to all the rights of its subrogors. In making the payments it has made on behalf of its employees and residents, Plaintiff did not act as a volunteer but rather acted under compulsion, for the protection of its interests, or as *parens patriae*.

II. Defendants

A. Manufacturer Defendants

63. At all relevant times, the Manufacturer Defendants each of whom is defined below, have manufactured, packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn to purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. The Marketing Defendants, at all times, have manufactured and sold prescription drugs without fulfilling their legal duty to prevent diversion and report suspicious orders.

1. Purdue Entities

64. Defendant PURDUE PHARMA, L.P. ("PPL") is a limited partnership organized

under the laws of Delaware with its principal place of business in Stamford, Connecticut.

65. Defendant PURDUE PHARMA, INC. (“PPI”) is a New York corporation with its principal place of business in Stamford, Connecticut.

66. Defendant THE PURDUE FREDERICK COMPANY, INC. (“PFC”) is a Delaware corporation with its principal place of business in Stamford, Connecticut.

67. PPL, PPI, and PFC, and their DEA registrant subsidiaries and affiliates (collectively, “PURDUE”), are authorized to do business in the State of New York. PURDUE is engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in the City of Syracuse, including the following:

Table 1. Purdue Opioids

Drug Name	Chemical Name	Schedule⁵²
OxyContin	Oxycodone hydrochloride extended release	Schedule II
MS Contin	Morphine sulfate extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Buprenorphine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone Hydrochloride	Schedule II

68. Oxycontin is PURDUE’s largest-selling opioid; and, since 2009, its national annual sales have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs. Sales of

⁵² Since passage of the CSA in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependences.

OxyContin (launched in 1996) went from a mere \$49 million in its first full year on the market to \$1.6 billion in 2002.

69. Purdue made thousands of payments to physicians nationwide, including, in New York State, ostensibly for activities including participating in speakers' bureaus, providing consulting services, assisting in post marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

70. In 2007, PURDUE and three of its executives pled guilty to federal criminal charges for misleading regulators, doctors and patients about OxyContin's risk of addiction and its potential to be abused.⁵³ None of this stopped PURDUE. In fact, PURDUE continued to create the false perception that opioids were safe and effective for long term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, PURDUE paid the fine after they were caught and continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

71. As referred to herein, the conduct of PURDUE, as hereinafter set forth, shall be deemed to include and encompass the conduct of any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and any of its officers, directors, employees, agents, representatives, and other persons acting on its behalf.

2. Cephalon Entities

72. Defendant CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

73. Defendant TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("TEVA LTD.") is

⁵³ Meier, Barry, "In Guilty Plea, OxyContin Maker to Pay \$600 Million," *The New York Times*, 10 May 2017, Web 24 Oct. 2017.

an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, TEVA, LTD. acquired CEPHALON, INC.

74. Defendant TEVA PHARMACEUTICALS USA, INC. (“TEVA USA”) is directly owned by (i) Orvet UK Unlimited (majority shareholder), which is directly owned by Teva Pharmaceuticals Europe B.V., which is directly owned by TEVA, LTD. and (ii) Teva Pharmaceutical Holdings Cooperative U.A. (minority shareholder), which is directly owned by IVAX LLC, a direct subsidiary of TEVA USA. TEVA USA is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. TEVA USA acquired CEPHALON in October 2011. Upon information and belief, CEPHALON, INC., TEVA LTD., and TEVA USA Defendants are authorized to do business in the State of New York.

75. CEPHALON, INC., TEVA LTD., and TEVA USA and their DEA registrant subsidiaries and affiliates (collectively, “CEPHALON”) work together to manufacture, promote, distribute and sell both brand name and generic versions of the opioids nationally and in the City of Syracuse, including the following:

Table 2. CEPHALON Opioids

Drug Name	Chemical Name	Schedule
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl citrate	Schedule II

76. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and in City of Syracuse.

77. Actiq and Fentora have been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.” Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain.

78. From 2000 forward, CEPHALON had made thousands of payments to physicians nationwide, including, in New York State, many of who were not oncologists and did not treat cancer pain, ostensibly for activities including participating in speakers' bureaus, providing consulting services, assisting in post marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

79. In 2008, CEPHALON, INC. pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.⁵⁴ None of this stopped CEPHALON. In fact, CEPHALON continued to create the false perception that opioids were safe and effective for long term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, CEPHALON, INC. paid the fine after they were caught and continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

80. TEVA LTD., TEVA USA, and CEPHALON, INC., work together closely to market and sell CEPHALON products nationally and in City of Syracuse. TEVA LTD. conducts all sales and marketing activities for CEPHALON, INC. in the United States through TEVA USA and has done so since its acquisition of CEPHALON, INC. in October of 2011. TEVA LTD. and TEVA USA hold out Actiq and Fentora as Teva products to the public. TEVA USA sells all former CEPHALON, INC. branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with CEPHALON opioids marketed and sold nationally and in City of Syracuse, discloses that the guide was submitted by TEVA USA, and directs physicians to contact TEVA USA to report adverse events. TEVA LTD. has directed CEPHALON, INC., to disclose that it is a wholly-owned subsidiary of TEVA LTD. on

⁵⁴ Department of Justice #08-860, September 29, 2008.

prescription savings cards distributed in New York, indicating TEVA LTD. would be responsible for covering certain co-pay costs. All of CEPHALON's promotional websites, including those for Actiq and Fentora, prominently display TEVA LTD.'s logo. TEVA LTD.'s financial reports list CEPHALON, INC.'s and TEVA USA's sales as its own, and its year-end report for 2012 - the year immediately following the CEPHALON acquisition - attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of CEPHALON's specialty sales." Through interrelated operations like these, TEVA LTD. operates in New York and the rest of the United States through its subsidiaries CEPHALON, INC. and TEVA USA. The United States is the largest of TEVA LTD.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of TEVA USA and CEPHALON, INC., TEVA LTD. would conduct those companies' business in the United States itself. Upon information and belief, TEVA LTD. directs the business practices of CEPHALON, INC. and TEVA USA, and their profits inure to the benefit of TEVA LTD. as controlling shareholder.

81. As referred to herein, the conduct of CEPHALON, as hereinafter set forth, shall be deemed to include and encompass the conduct of any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and any of its officers, directors, employees, agents, representatives, and other persons acting on its behalf.

3. Janssen Entities

82. Defendant JOHNSON & JOHNSON ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey, and is a publicly held corporation.

83. Defendant JANSSEN PHARMACEUTICALS, INC. ("JANSSEN PHARMACEUTICALS") is a Pennsylvania corporation with its principal place of business in

Titusville, New Jersey, and is a wholly owned corporate subsidiary of J&J. J&J corresponds with the FDA regarding Janssen's products. JANSSEN PHARMACEUTICALS was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

84. Defendant ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. ("OMP"), now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

85. Defendant JANSSEN PHARMACEUTICA, INC. ("JANSSEN PHARMACEUTIC") now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

86. JANSSEN PHARMACEUTICA, INC. ("JANSSEN PHARMACEUTICA"), now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

87. J&J is the only company that owns more than 10% of JANSSEN PHARMACEUTICALS stock. Upon information and belief, J&J controls the sale and development of JANSSEN PHARMACEUTICALS drugs and JANSSEN PHARMACEUTICALS profits inure to J&J's benefit.

88. J&J, JANSSEN PHARMACEUTICALS, OMP, and JANSSEN PHARMACEUTICA (collectively, "JANSSEN"), upon information and belief, are authorized to do business in the State of New York, and along with their DEA registrant subsidiaries and affiliates are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in the City of Syracuse, including the following:

Table 3. Janssen Opioids

Drug Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II
Nucynta ⁵⁵	Tapentadol extended release	Schedule II
Nucynta ER	Tapentadol	Schedule II

89. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

90. JANSSEN has made thousands of payments to physicians nationwide, including, in New York State, ostensibly for activities including participating in speakers' bureaus, providing consulting services, assisting in post marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

91. Information from the U.S. Department of Justice's Office of the Inspector General shows that J&J made payments to prescribers but does not indicate which drug was being promoted when J&J made these payments. At least one prescriber who previously served on Janssen's speaker's bureau received payment for speaking fees, meals, and travel from J&J. Upon information and belief, J&J would have similarly made payments to other participants in Janssen's speaker's bureaus.

92. JANSSEN, like many other companies, has a corporate code of conduct, which clarified the organization's mission, values and principles. JANSSEN'S employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on JANSSEN as a pharmaceutical subsidiary of J&J. Documents posted on J&J's websites confirm J&J's control of development and marketing of opioids by JANSSEN. JANSSEN's website "Ethical Code for the Conduct of Research and Development" names only J&J and does not mention

⁵⁵ Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

JANSSEN anywhere in the documents. The “Ethical Code of the Conduct of Research and Development” posted on JANSSEN’s website is J&J’s companywide ethical code, which it requires all of its subsidiaries to follow.

93. The “Every Day Health Care Compliance Code of Conduct” posted on JANSSEN’s website is a J&J company-wide document that describes JANSSEN as one of the “Pharmaceutical Companies of Johnson & Johnson” and as one of the “Johnson & Johnson Pharmaceutical Affiliates.” It governs how “[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates,” including those of JANSSEN, “market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates’ products.” All JANSSEN officers, directors, employees, and sales associates must certify that they have “read, understood and will abide by” the code. The code governs all of the forms of marketing at issue in this case.

94. As referred to herein, the conduct of JANSSEN, as hereinafter set forth, shall be deemed to include and encompass the conduct of any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and any of its officers, directors, employees, agents, representatives, and other persons acting on its behalf.

4. Depomed, Inc.

95. Defendant, DEPOMED, INC., now known as ASSERTIO THERAPEUTICS, INC. (“DEPOMED”) is a California corporation authorized to do business in the State of New York, with its principle place of business in Newark, California.

96. DEPOMED is a specialty pharmaceutical company that commercializes products for pain and neurology related disorders. DEPOMED, along with their DEA registrant subsidiaries and affiliates are or have been engaged in the manufacture, promotion, distribution, and sale of

opioids nationally and in Plaintiff's community, including the following:

Table 4. Depomed Opioids

Drug Name	Chemical Name	Schedule
Lazanda	Fentanyl	Schedule II
Nucynta ⁵⁶	Tapentadol extended release	Schedule II
Nucynta ER	Tapentadol	Schedule II

97. In April of 2015, DEPOMED, Inc. acquired the U.S. rights to the NUCYNTA franchise from JANSSEN PHARMACEUTICALS for \$1.05 billion. The NUCYNTA franchise includes: NUCYNTA[®] ER (tapentadol) extended release tablets indicated for the management of pain, including neuropathic pain associated with diabetic peripheral neuropathy (DPN), severe enough to require daily, around-the-clock, long-term opioid treatment; NUCYNTA[®] (tapentadol), an immediate release version of tapentadol, for management of moderate to severe acute pain in adults; and NUCYNTA (tapentadol) oral solution, an approved oral form of tapentadol that has not been launched.

98. Upon the consummation of the transaction on April 2, 2015, DEPOMED acquired (i) rights to commercialize the NUCYNTA products in the United States, and (ii) certain other assets relating to the NUCYNTA products, including finished goods product inventory and certain manufacturing equipment. In addition, Janssen Pharma assigned to the Company all of its rights and obligations under the License Agreement (U.S.) (the License Agreement) by and among Janssen Pharma, Janssen Research & Development, LLC and Grunenthal GmbH (Grunenthal) pursuant to which Janssen has a royalty-bearing license to certain Grunenthal patents and other intellectual property rights covering the commercialization of the Products in the United States.

99. NUCYNTA is now the flagship asset in DEPOMED'S growing portfolio of pain

⁵⁶ Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

and neurology specialty pharmaceuticals. NUCYNTA ER is the only opioid FDA-approved for both chronic pain and neuropathic pain associated with diabetic peripheral neuropathy (DPN). NUCYNTA ER has not been fully launched for the DPN indication; and DEPOMED stated in 2015 that the product's clinical benefits had not been fully appreciated in the United States.

100. DEPOMED also indicated, after the acquisition, that it expected NUCYNTA to benefit from synergies with the company's expanded commercial infrastructure. DEPOMED'S current sales force overlaps approximately 70% of the NUCYNTA prescriber base, allowing the company to capitalize on well-established relationships with key prescribers. According to DEPOMED, the expanded sales force for NUCYNTA of over 250 representatives, is over 3 times the size of the prior sales effort and will cover an even higher percentage of the prescribers.

101. Upon information and belief, DEPOMED has made thousands of payments to physicians nationwide, including, in New York State, ostensibly for activities including participating in speakers' bureaus, providing consulting services, assisting in post marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

102. As referred to herein, the conduct of DEPOMED, as hereinafter set forth, shall be deemed to include and encompass the conduct of any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and any of its officers, directors, employees, agents, representatives, and other persons acting on its behalf.

5. Endo Entities

103. Defendant ENDO HEALTH SOLUTIONS INC. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania; and, upon information and belief, is authorized to do business in the State of New York. EHS is an indirectly owned subsidiary

of Endo International, plc, an Irish publicly held limited company that has global headquarters in Dublin, Ireland and U.S. headquarters in Malvern, Pennsylvania.

104. Defendant ENDO PHARMACEUTICALS, INC. (“EPI”) is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Upon information and belief, EPI is authorized to do business in the State of New York. EPI is an indirectly owned subsidiary of Endo International, plc, an Irish publicly held limited company that has global headquarters in Dublin, Ireland and U.S. headquarters in Malvern, Pennsylvania.

105. Defendant ENDO GENERICS HOLDING, INC. (“EGH”) is a foreign business corporation organized and existing under the laws of the State of Delaware, and is authorized to do business in the State of New York, with its principal place of business located in Chestnut Ridge, New York. EGH is an indirectly owned subsidiary of Endo International, plc, an Irish publicly held limited company that has global headquarters in Dublin, Ireland and U.S. headquarters in Malvern, Pennsylvania.

106. Defendant PAR PHARMACEUTICAL COMPANIES, INC. N/K/A ENDO GENERICS HOLDING, INC. (“PPC”) is a foreign business corporation organized and existing under the laws of the State of Delaware, and is authorized to do business in the State of New York, with its principal place of business located in Chestnut Ridge, New York. PPC is an indirectly owned subsidiary of Endo International, plc, an Irish publicly held limited company that has global headquarters in Dublin, Ireland and U.S. headquarters in Malvern, Pennsylvania. PPC was acquired by Endo International, plc in September of 2015 and is an operating company of Endo International, plc.

107. Defendant PAR PHARMACEUTICAL, INC. (“PPI”) is a domestic business

corporation organized and existing under the laws of the State of New York with its principal place of business located in Chestnut Ridge, New York. PPI is a wholly owned subsidiary of PPC f/k/a Par Pharmaceutical Holdings, Inc., and an indirectly owned subsidiary of Endo International, plc, an Irish publicly held limited company that has global headquarters in Dublin, Ireland and U.S. headquarters in Malvern, Pennsylvania.

108. EHS, EPI, EGH, PPC and PPI and their DEA registrant subsidiaries and affiliates (collectively, “ENDO”), work together to manufacture, promote, distribute and sell opioids nationally and in the City of Syracuse, including the following:

Table 4. ENDO Opioids

Drug Name	Chemical Name	Schedule
Opana ER	Oxymorphone hydrochloride extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
Zydone	Hydrocodone and acetaminophen	Schedule II

109. Opioids made up roughly \$403 million of ENDO’s overall revenues of \$3 billion in 2012. Opana ER yielded revenue of \$1.15 billion from 2010 to 2013, and it accounted for 10% of ENDO’s total revenue in 2012.

110. ENDO made thousands of payments to physicians nationwide, including, in New York State, ostensibly for activities including participating in speakers’ bureaus, providing consulting services, assisting in post marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

111. The State of New York, in a 2016 settlement agreement with ENDO, found that

opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." ENDO had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State found that ENDO had no evidence for that statement. The Agreement required ENDO to cease all misrepresentations regarding the properties of Opana ER, to describe accurately the risk of addiction to Opana ER and to summarize studies regarding Opana ER on its website. Pursuant to the Agreement, ENDO was required to create a program that will prevent its sales staff from promoting this powerful narcotic painkiller to healthcare providers who may be involved in the abuse and illegal diversion of opioids. Consistent with this, ENDO agreed not to "make statements that ... opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York.⁵⁷ None of this stopped ENDO. In fact, ENDO continued to create the false perception that opioids were safe and effective for long term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, ENDO, even after they reached the Settlement Agreement, continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

112. In 2017, the U.S. Food and Drug Administration requested "that ENDO Pharmaceuticals remove its opioid pain medication, reformulated Opana ER (oxymorphone hydrochloride), from the market."⁵⁸ The agency sought removal "based on its concern that the benefits of the drug may no longer outweigh its risks."⁵⁹

⁵⁷ Press Release, March 3, 2016, A.G. Schneiderman Announces Settlement with ENDO Health Solutions, Inc. & ENDO Pharmaceuticals, Inc. Over Marketing of Prescription Opioid Drugs; Web. 6 Dec 2017.

⁵⁸ FDA News Release, "FDA Requests Removal of Opana ER for Risks Related to Abuse, June 8, 2017, U.S. Food & Drug Administration, 8 June 2017. Web. 10 Oct. 2017.

⁵⁹ *Id.*

113. ENDO also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

114. As referred to herein, the conduct of ENDO, as hereinafter set forth, shall be deemed to include and encompass the conduct of any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and any of its officers, directors, employees, agents, representatives, and other persons acting on its behalf.

6. Mallinckrodt Entities

115. Defendant MALLINCKRODT PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom and maintains a U.S. headquarters in St. Louis, Missouri. MALLINKRODT PLC was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to MALLINKRODT, PLC in June of that year. MALLINKRODT PLC also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

116. Defendant MALLINCKRODT, LLC is a foreign limited liability company organized and existing under the laws of the State of Delaware and it is authorized to do business in the State of New York. MALLINCKRODT, LLC is indirectly a wholly owned subsidiary of MALLINCKRODT, PLC, with offices for its principal place of business located at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

117. Defendant SPECGX, LLC, is a foreign limited liability company organized and existing under the laws of the State of Delaware and it is authorized to do business in the State of New York. Defendant SPECGX, LLC is indirectly a wholly owned subsidiary of

MALLINCKRODT, PLC, with offices for its principal place of business located at 3600 North Second Street, Saint Louis, Missouri.

118. Defendant MALLINCKRODT BRAND PHARMACEUTICALS, INC. is a foreign corporation organized and existing under the laws of the State of Delaware. MALLINCKRODT BRAND PHARMACEUTICALS, INC. is indirectly a wholly owned subsidiary of MALLINCKRODT, PLC, with offices for its principal place of business located at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

119. Defendant MALLINCKRODT ENTERPRISES, LLC is a foreign limited liability company organized and existing under the laws of the State of Delaware and is authorized to do business in New York State. MALLINCKRODT ENTERPRISES, LLC is indirectly a wholly owned subsidiary of MALLINCKRODT, PLC, with offices for its principal place of business located at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

120. Defendant MALLINCKRODT ENTERPRISES HOLDINGS, INC. is a foreign corporation organized and existing under the laws of the State of California and is authorized to do business in New York State. MALLINCKRODT ENTERPRISES HOLDINGS, INC. is indirectly a wholly owned subsidiary of MALLINCKRODT, PLC, with offices for its principal place of business located at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

121. MALLINCKRODT, PLC, MALLINCKRODT, LLC, SPECGX, LLC, MALLINCKRODT BRAND PHARMACEUTICALS, INC, MALLINCKRODT ENTERPRISES, LLC, MALLINCKRODT ENTERPRISES HOLDINGS, INC., and their DEA registrant subsidiaries and affiliates (collectively “MALLINCKRODT”), are engaged in the manufacture, promotion, and distribution of Roxycodone and Oxycodone, among other drugs, throughout the United States and in the City of Syracuse. MALLINKRODT is the largest U.S. supplier of opioid pain medications and

among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

Table 5. MALLINCKRODT Opioids

Drug Name	Chemical Name	Schedule
Exalgo	Hydromorphone HCl extended release	Schedule II
Roxicodone	Oxycodone hydrochloride	Schedule II

122. Upon information and belief, MALLINCKRODT made thousands of payments to physicians nationwide, including, in New York State, ostensibly for activities including participating in speakers' bureaus, providing consulting services, assisting in post marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

123. While it has sought to develop its branded opioid products, MALLINCKRODT has long been a leading manufacturer of generic opioids. MALLINCKRODT estimated that in 2015 it received approximately 25% of the DEA's entire annual quota for controlled substances that it manufactures. MALLINCKRODT also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medication. See Mallinckrodt, plc, Annual Report (Form 10-K), at 5 (November 29, 2016).

124. MALLINCKRODT operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

125. In 2017, The Department of Justice (DOJ) fined MALLINCKRODT \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating

recordkeeping requirements.⁶⁰ None of this stopped MALLINCKRODT. In fact, MALLINCKRODT continued to create the false perception that opioids were safe and effective for long term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, MALLINCKRODT, even after they were fined, continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

126. As referred to herein, the conduct of MALLINKRODT, as hereinafter set forth, shall be deemed to include and encompass the conduct of any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and any of its officers, directors, employees, agents, representatives, and other persons acting on its behalf.

7. Actavis Entities

127. Defendant ALLERGAN PLC f/k/a ACTIVAS PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Defendant ACTAVIS PLC acquired Defendant ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC in June 2015.

128. Defendant ALLERGAN FINANCE, LLC f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC. is a foreign limited liability company organized and existing under the laws of the State of Nevada and has its principal place of business located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. The Defendant ACTAVIS, INC. was acquired by Defendant WATSON PHARMACEUTICALS, INC. in October 2012, and the combined company changed its name to ACTAVIS, INC. as of January 2013 and then ACTAVIS PLC in October 2013. The Defendant ALLERGAN FINANCE, LLC f/k/a ACTAVIS, INC., f/k/a WATSON

⁶⁰ Press Release, "MALLINCKRODT Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations," U.S. Dept. of Justice, 11 July 2017. Web. 16 Sept. 2017.

PHARMACEUTICALS, INC. is an indirect wholly owned subsidiary of ALLERGAN, PLC through a chain of affiliated non-public entities.

129. Defendant WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Defendant ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) and an indirect subsidiary of TEVA LTD., which is publicly traded. In August of 2016, ALLERGAN PLC sold the Generics division of the company to TEVA LTD.

130. Defendant ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey, and is a wholly-owned subsidiary of Defendant ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) and an indirect subsidiary of TEVA LTD., which is publicly traded. In August of 2016, ALLERGAN PLC sold the Generics division of the company to TEVA LTD.

131. Defendant ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC. is a Delaware corporation with its principal place of business in New Jersey and is a wholly-owned subsidiary of Defendant ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) and an indirect subsidiary of TEVA LTD., which is publicly traded. In August of 2016, ALLERGAN PLC sold the Generics division of the company to TEVA LTD.

132. Each of these defendants is owned by Defendant ALLERGAN PLC and/or TEVA LTD, which uses them to market and sell its drugs in the United States. Defendant ALLERGAN PLC and/or TEVA LTD exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit.

133. ALLERGAN PLC, ACTAVIS PLC, ALLERGAN FINANCE, LLC f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES,

INC. ACTAVIS LLC, ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC., (collectively “ACTAVIS”), upon information and belief, are authorized to do business in the State of New York. ACTAVIS, and their DEA registrant subsidiaries and affiliates, manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana in the United States. ACTAVIS acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

Table 6. Actavis Opioids

Drug Name	Chemical Name	Schedule
Kadian	Morphine sulfate extended release	Schedule II
Norco	Hydrocodone bitartrate And acetaminophen	Schedule II

134. Upon information and belief, ACTAVIS made thousands of payments to physicians nationwide, including, in New York State, ostensibly for activities including participating in speakers’ bureaus, providing consulting services, assisting in post marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

135. As referred to herein, the conduct of ACTAVIS, as hereinafter set forth, shall be deemed to include and encompass the conduct of any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and any of its officers, directors, employees, agents, representatives, and other persons acting on its behalf.

8. Insys Therapeutics, Inc.

136. INSYS Therapeutics, Inc. (referred to here as “INSYS”) is a Delaware corporation with its principal place of business in Chandler, Arizona.

137. INSYS manufactures, promotes, sells, and distributes the opioid fentanyl also known as Subsys, in the United States, including in New York. Subsys is a fentanyl sublingual (under the tongue) spray that has been approved by the FDA only for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”⁶¹

Table 7. Insys

Drug Name	Chemical Name	Schedule
Subsys	fentanyl sublingual (under the tongue) spray	Schedule II

138. Subsys is 100 times stronger than morphine and was approved by the FDA to treat patients with cancer who had “breakthrough” pain, that is pain which other narcotics are not addressing.

139. Subsys was INSYS’s only marketed product from March 2012 until July 2017. INSYS revenues totaled over \$240 million in 2016 and \$330 million in 2015. INSYS is a licensed pharmacy Controlled Substance Facility, wholesaler and distributor, and, upon information and belief, authorized to do business in the State of New York.

140. INSYS’s founder and owner was recently arrested and charged, along with other INSYS executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. Other INSYS executives and managers were previously indicted. None of this stopped INSYS. In fact, INSYS continued to create the false perception that Subsys was safe and effective for long term use, even after being caught, by using its medication to circumvent the system. In short, INSYS even after they were caught,

⁶¹ *Highlights of Prescribing Information, SUBSYS® (fentanyl sublingual spray), CII (2016)*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202788s016lbl.pdf.

continued to do business as usual, deceptively marketing and selling billions of dollars of their medication each year.

141. Collectively, Purdue, Cephalon, Janssen, Depomed, Endo, Actavis, Mallinckrodt and Insys are referred to as “Manufacturer Defendants”.

B. Distributor Defendants

142. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state laws. The Distributor Defendants are engaged in “wholesale distribution” as defined under federal and state laws. Plaintiff alleges the unlawful conduct by the Distributor Defendants as a substantial cause for the volume of prescription opioids plaguing the Plaintiff’s community.

1. Amerisourcebergen Drug Corporation

143. Defendant AMERISOURCEBERGEN DRUG CORPORATION (“AMERISOURCEBERGEN”) is a Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania. AMERISOURCEBERGEN is the second largest pharmaceutical distributor in North America. AMERISOURCEBERGEN does substantial business in the State of New York where it distributes pharmaceuticals in City of Syracuse.

144. AMERISOURCEBERGEN, through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Plaintiff’s community.

145. As referred to herein, the conduct of AMERISOURCEBERGEN, as hereinafter set

forth, shall be deemed to include and encompass the conduct of any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and any of its officers, directors, employees, agents, representatives, and other persons acting on its behalf.

2. Cardinal Health, Inc.

146. Defendant CARDINAL HEALTH, INC. (“CARDINAL” OR “CARDINAL HEALTH”) is an Ohio Corporation with its principal place of business in Dublin, Ohio.

147. CARDINAL, through its various DEA registered subsidiaries and affiliated entities, distributes pharmaceutical drugs, including opioids, throughout the country, including in Plaintiff’s community.

148. CARDINAL describes itself as a “global, integrated health care services and products company,” and is the fifth largest company by revenue in the United States, with annual revenue of \$121 billion in 2016. Based on CARDINAL’s own estimates, one of every six pharmaceutical products dispensed to United States’ patients travels through the Cardinal Health network.

149. In 2013, CARDINAL paid a \$44 million fine for failing to report suspicious orders of controlled substances. CARDINAL does substantial business in the State of New York and distributes pharmaceuticals in the City of Syracuse.⁶² None of this stopped CARDINAL. In fact, even after they were fined, CARDINAL continued business as usual, unlawfully distributing and selling billions of dollars of opioids each year and failed to report suspicious orders of controlled substances in violation of federal and state laws.

150. As referred to herein, the conduct of CARDINAL, as hereinafter set forth, shall be

⁶² CARDINAL HEALTH Media Room, “CARDINAL HEALTH Announces Civil Settlement with DOJ”, December 23, 2016.

deemed to include and encompass the conduct of any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and any of its officers, directors, employees, agents, representatives, and other persons acting on its behalf.

3. McKesson Corporation

151. Defendant MCKESSON CORPORATION (“MCKESSON”) is a Delaware Corporation with its principal place of business located in San Francisco, California.

152. MCKESSON is fifth on the list of Fortune 500 companies, with annual revenue of \$191 billion in 2016, and is the largest pharmaceutical distributor in North America. MCKESSON delivers approximately one-third of all pharmaceuticals used in North America.

153. MCKESSON, through its various DEA registered subsidiaries and affiliated entities, distributes pharmaceutical drugs, including opioids, throughout the country, including in Plaintiff’s community.

154. In January of 2017, MCKESSON agreed to pay \$150 million in fines and to suspend sales from four distribution centers to settle allegations that the company violated federal law and failed to design an effective system to detect “suspicious orders” from pharmacies for powerful painkillers such as oxycodone, as required by the Controlled Substances Act.⁶³ This is the second settlement for MCKESSON, as they paid a \$13.25 million settlement in 2008, over similar allegations.⁶⁴ None of this stopped MCKESSON. In fact, even after they were fined, MCKESSON continued business as usual, unlawfully distributing and selling billions of dollars of opioids each year and failed to report suspicious orders of controlled substances in violation of federal and state

⁶³ *The Washington Post*, “McKesson, nation’s largest drug distributor, to pay \$150 million in fines in opioid settlement, January 18, 2017.

⁶⁴ *Id.*

laws.

155. As referred to herein, the conduct of MCKESSON, as hereinafter set forth, shall be deemed to include and encompass the conduct of any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and any of its officers, directors, employees, agents, representatives, and other persons acting on its behalf.

4. H.D. Smith, LLC

156. DEFENDANT H.D. SMITH, LLC f/k/a H.D. SMITH WHOLESALE DRUG COMPANY (“H.D. SMITH”), is a Delaware limited liability corporation that is authorized to do business in New York State with its principal place of business in Springfield, Illinois. H.D. SMITH through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Plaintiff’s community. H.D. Smith is a wholly owned subsidiary of AMERISOURCEBERGEN.

157. H.D. SMITH is a distributor of wholesale brand, generic and specialty pharmaceuticals. At all relevant times, H.D. SMITH distributed prescription opioids throughout the United States, including in Plaintiff’s community.

158. As referred to herein, the conduct of H.D. SMITH, as hereinafter set forth, shall be deemed to include and encompass the conduct of any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and any of its officers, directors, employees, agents, representatives, and other persons acting on its behalf.

5. Anda, Inc.

159. DEFENDANT ANDA, INC. (“ANDA”), is a Florida corporation that is authorized

to business in New York State with its principal place of business located in Weston, Florida. ANDA, through its various DEA registered subsidiaries and affiliated entities, including but not limited to, ANDA Pharmaceuticals, Inc., is the fourth largest distributor of generic pharmaceuticals in the United States. ANDA is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Plaintiff's community.

160. In October of 2016, Defendant TEVA acquired ANDA from ALLERGAN, PLC (i.e. Defendant Actavis), for \$500 million in cash. At all relevant times, ANDA distributed prescription opioids throughout the United States, including in Plaintiff's community.

161. As referred to herein, the conduct of ANDA, as hereinafter set forth, shall be deemed to include and encompass the conduct of any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and any of its officers, directors, employees, agents, representatives, and other persons acting on its behalf.

6. Rite Aid

162. RITE AID CORPORATION is a Delaware corporation that is authorized to do business in New York State with its principal place of business located in Camp Hill, Pennsylvania. RITE AID CORPORATION, through its various DEA registered subsidiaries and affiliated entities, including but not limited to, Defendant, RITE AID OF NEW YORK, INC., a New York corporation with its principal offices located in Camp Hill, Pennsylvania, and Defendant, RITE AID OF MARYLAND, INC., d/b/a RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC., a Maryland corporation with its principal offices located in Camp Hill, Pennsylvania, are licensed distributor of prescription opioids in the United States (collectively, "RITE AID"). RITE AID is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in

Plaintiff's community.

7. KPH Healthcare Services, Inc.

163. KPH HEALTHCARE SERVICES, INC. is a New York corporation with its principal place of business located in Gouverneur, New York. KPH HEALTHCARE SERVICES, INC. through its various DEA registered subsidiaries and affiliated entities, is licensed to distribute prescription opioids in Plaintiff's municipality.

8. WalMart, Inc.

164. DEFENDANT WALMART, INC. f/k/a Wal-Mart Store, Inc. ("WALMART"), is a Delaware corporation that is authorized to do business in New York State with its principal place of business located in Bentonville, Arkansas. WALMART, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all relevant times, WALMART distributed prescription opioids throughout the United States, including, in Plaintiff's community.

165. Collectively, Defendants RITE AID, KPH HEALTHCARE SERVICES and WALMART are referred to as "National Retail Pharmacies."

166. Collectively, Defendants AMERISOURCEBERGEN DRUG CORPORATION, CARDINAL HEALTH, INC., MCKESSON CORPORATION, H.D. SMITH, LLC f/k/a H.D. SMITH WHOLESALE DRUG COMPANY, ANDA, INC. and the National Retail Pharmacies are collectively referred to as the "Distributor Defendants."

C. Doe Entities

167. Plaintiff lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names of JOHN DOE, JOHN DOES, OR JOHN DOE CORPORATION, being a fictitious

name(s) used to designate a person, persons, partnership, sole proprietorship, corporation or other entity, who is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein. The Plaintiff will amend this Complaint to show their true names and capacities if and when they are ascertained.

168. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale and/or dispensing of opioids.

D. Agency and Authority

169. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleges herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' business affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority

JURISDICTION AND VENUE

170. This Court has jurisdiction over this action under 28 U.S.C. §1331 based on the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §1961, *et seq.* ("RICO").

171. This Court also has supplemental jurisdiction over Plaintiffs' state-law claims under 28 U.S.C. §1367 because those claims are so related to Plaintiffs' federal claims that they form part of the same cause or controversy.

172. This Court has personal jurisdiction over Defendants because they conduct business in the State of New York, purposefully direct or directed their actions toward New York State, consensually submitted to the jurisdiction of New York State when obtaining a manufacturer or

distributor license, and have the requisite minimum contacts with New York State necessary to constitutionally permit the Court to exercise jurisdiction. Further, this Court has personal jurisdiction over Defendants because they carry on a continuous and systemic part of their general business within New York State, have transacted business with New York entities and residents, and have caused grave harm in New York State and City of Syracuse as a result.

173. Venue is proper in this District under 28 U.S.C. §1391 and 18 U.S.C. §1965 since a substantial part of the events or omissions giving rise to the claim occurred in, and each Defendant transacted affairs and conducted activity that gives rise to the claim of relief in, this District.

JURY DEMAND

174. The Plaintiff demands a jury trial pursuant to Federal Rule of Civil Procedure 38.

FACTUAL ALLEGATIONS

I. Opioids Are Addictive.

175. The pain-relieving properties of opium have long been recognized, and so has the potential for abuse and addiction. Opioids are related to illegal drugs like opium and heroin.

176. Due to concerns about addictive properties, opioids have been regulated at the federal level as controlled substances by the DEA since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and “[s]erious, life-threatening, or fatal respiratory depression,” as the result of an excessive overdose.

177. Prior to the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, surgical pain during recovery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients’ ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed

tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

178. In 1986, Russell Portenoy, MD, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, while serving as a top spokesperson for drug companies, published an article reporting that “[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.”⁶⁵

179. Writing in 1994, Russell Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

*The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*⁶⁶

According to Dr. Russell Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”⁶⁷

⁶⁵ Portenoy, R. & Foley, K., “Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases,” 25(2) Pain 171 (1986).

⁶⁶ Portenoy, R., “Opioid Therapy for Chronic Nonmalignant Pain: Current Status,” 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

⁶⁷ Id.

180. For all the reasons outlined by Dr. Russell Portenoy, and in the words of one researcher from the University of Washington in 2012, and quoted by a Harvard researcher the same year, “it did not enter [doctors’] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids, because if there were any, we almost never saw them.”⁶⁸

181. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction to which he has become accustomed – up to and including doses that are “frighteningly high.”⁶⁹ At higher doses, the effects of withdrawal are more substantial leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

182. In 2013, the FDA warned of the “grave risks” of opioids, including “addiction, overdose, and even death.” The FDA further warned, “[e]ven proper use of opioids under medical supervision can result in life- threatening respiratory depression, coma, and death.” Because of those grave risks, the FDA said that long-acting or extended release opioids “should be used only when alternative treatments are inadequate.”⁷⁰

183. The facts on which the FDA relied were well known to Manufacturer Defendants in the 1990s when their deceptive marketing began.

184. For profit sake, each Defendant took advantage of the lucrative market for chronic

⁶⁸ Loeser, J., “Five Crises in Pain Management, *Pain Clinical Updates*,” 2012; 20 (1):1–4 (cited by I. Kissin, *Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?*, 6 *J. Pain Research* 513, 514 (2013)).

⁶⁹ Katz, M., “Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith,” 170(16) *Archives of Internal Med.* 1422 (2010).

⁷⁰ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013) (*emphasis in original*).

pain patients and developed a well-funded marketing scheme based on deceptive practices. Each Defendant used both direct marketing and unbranded advertising disseminated by so called independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use, which statements only benefited each Defendant but also other Defendants and opioid manufacturers. These statements, however, were unsupported by and contrary to the scientific evidence and to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible and vulnerable patient populations.

II. No Scientific Evidence Supports Long Term Use of Opioids

185. There is no scientific evidence supporting the safety or efficacy of opioids for long-term use.⁷¹ Manufacturer Defendants are aware of the lack of such scientific evidence. While promoting opioids to treat chronic pain, Manufacturer Defendants failed to disclose the lack of evidence to support their use long-term and have failed to disclose the substantial scientific evidence that chronic opioid therapy makes patients sicker.

186. There are no controlled studies of the use of opioids beyond 12 weeks, and no evidence that opioids improve patients' pain and function long-term.⁷² A 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use.⁷³

187. Substantial evidence exists that opioid drugs are ineffective to treat chronic pain, and actually worsen patients' health. A 2006 study-of-studies found that opioids as a class did not

⁷¹ See, e.g., S. Quinones, *Dreamland* 92 (2015) (noting that researchers other than Manufacturer Defendants' KOLs "had been issuing papers saying that many chronic-pain patients using opiate invariably ended up addicted").

⁷² See, e.g., Dowell, Deborah MD et al., "CDC Guideline for Prescribing Opioids for Chronic Pain," *Centers for Disease Control and Prevention*, 18 Mar. 2016. Web. 24 Oct. 2017.

⁷³ Martell, BA. et al., "Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction," *Ann Intern Med*. 2007 Jan 16; 146(2):116-27.

demonstrate improvement in functional outcomes over other non-addicting treatments.⁷⁴

188. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.⁷⁵

189. While opioids may work acceptably well for a while, when used on a long term basis, patient function declines, as does general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses cannot function normally.⁷⁶

190. Studies of the use of opioids long-term for chronic lower back pain cannot demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity. This is due partly to addiction and other side effects.⁷⁷

III. Defendant's Scheme to Realize Blockbuster Profits

191. Before Manufacturer Defendants began the marketing campaign that is the subject of this complaint, generally accepted standards of medical practice dictated that opioids should only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer

⁷⁴ Furlan, AD. et al., "Opioids for Chronic Noncancer Pain: a Meta-Analysis of Effectiveness and Side Effects," *CMAJ*. 2006 May 23;174(11):1589-94. This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. See Seal, Karen et al., "Association of Mental Health Disorders with Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan," *JAMA*. 2012;307(9):940-947.

⁷⁵ "Effects of Opioid Abuse on Your Mental Health," *Disorders.org*. Web. 24 Oct. 2017.

⁷⁶ See Rubenstein, Andrea, "Are we Making Pain Patients Worse?" *Sonoma Medicine*. Web. 25 Oct. 2017.

⁷⁷ Freud, J. et al., "How Effective are Opioids for Chronic Low Back Pain?," *J. Fam. Pract.*, 64(9):584-585 (Sept. 2015).

or palliative care.

192. Manufacturer Defendants promoted that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic pain.

193. The market for short-term pain relief, however, is significantly more limited than the market for long-term chronic pain relief. Manufacturer Defendants recognized that if they could sell opioids not just for short term pain relief but also for long-term chronic pain relief, they could achieve blockbuster levels of sales and their profits.

194. Each Defendant has been engaged in a fraudulent and illegal scheme to cause increased prescribing and reimbursement for their opioid drugs. Plaintiff and other municipalities were intended victims of these fraudulent schemes.

195. The misrepresentations and omissions key to expanding the prescription market for opioid drugs all focused on the necessity, efficacy and risks associated with long-term use for the treatment of chronic pain.

196. The Manufacturer Defendants and their allies (co-promoters, third-party marketers and promoters, physician thought leaders, key opinion leaders (“KOLs”), medical ghost writers, medical marketing firms, digital marketers, and Front Groups) invented an “untreated pain epidemic” requiring urgent attention from not only the medical community, but from patients who had decided to live with some chronic pain. Luckily, an uninterrupted life-long regimen of opioid drugs was the perfect solution to the nation’s chronic pain woes.

197. The Manufacturer Defendants promulgated the fraudulent messaging that concerns about addiction were overblown: simple screening and monitoring tools would prevent addiction, which incidentally was all the more unlikely due to incredible advancements in abuse-deterrent pill

technology. Even if a patient exhibited all the classic symptoms of addiction, those were merely signs that his or her pain was undertreated: the solution was more opioid drugs, often ending in an uninterrupted life-long regimen.

198. To disseminate this wildly inaccurate message and grow the prescription market for opioid drugs, the Manufacturer Defendants and their allies employed a coordinated and multi-faceted marketing campaign, utilizing different tools and aimed at different targets to facilitate aggressive direct marketing to physicians.

199. First, prescribing physicians were targeted with these deceptive messages. The messages originated from a variety of sources. Some could recognize as originating from the Manufacturer Defendants, such as sales representative pitches, medical journal advertising, and manufacturer websites. Other deceptive messages, however, came from peer physician experts, trade organizations, or hosts of medical education programs that seemed independent but were actually controlled by the Manufacturer Defendants. Prescribing health care professionals were also enticed with financial payments or other compensation (such as free trips) as rewards for prescribing opioid drugs. These associations-in-fact are referred to herein as physician pull-through marketing enterprises or schemes and are discussed in greater detail, *infra*.

200. Second, the Manufacturer Defendants also set out to corrupt scientific literature in an effort to expand the prescription market for opioid drugs. They employed an endless chain of circular citations in an effort to lend veracity to their unsubstantiated claims. They helped draft guidelines and disseminate medical board standards, and then utilized their Front Group organizations to create medical consensus around those standards. They further paid physicians, Front Groups, and consultants to draft academic or technical papers lauding the safety and efficacy of Opioid Drugs in treating long-term chronic pain. These actors - all paid by the Manufacturer

Defendants - often cited and relied on one another's work in an effort to create the illusion of peer review. These associations-in-fact are referred to herein as scientific literature marketing enterprises or schemes and are discussed in greater detail, *infra*.

201. Third, the Manufacturer Defendants also targeted vulnerable consumers (those suffering with chronic pain) with false and misleading marketing to increase patient demand for opioid drugs. These efforts consisted of, *inter alia*, patient brochures, patient-oriented websites, starter coupons or co-pay assistance, media campaigns and initiatives, and the use of Front Groups masquerading as patient advocacy organizations. These associations-in-fact are referred to as consumer pull-through marketing enterprises or schemes and are discussed in greater detail, *infra*.

202. Fourth, all Defendants worked tirelessly to manufacture, market, promote, distribute, and sell each of the opioid drugs. This often consisted of generating false and misleading information provided to third party payors to determine coverage, such as drug dossiers, treatment guidelines, and scientific literature. Once the Manufacturer Defendants obtained (and/or maintained) formulary access, it was key to "pull-through" prescriptions by marketing this favorable formulary status to prescribing health care professionals. This meant that the Manufacturer Defendants' sales representatives sold third party payor formulary status to health care professionals as part of pulling-through formulary prescriptions. To the extent that third party payors attempted to impose formulary limitations, the Manufacturer Defendants' representatives would then "teach" prescribing health care professionals various techniques to secure more favorable health plan coverage on behalf of their patients. Health plan efforts to control their formularies through preferred tier placement were stymied by the Manufacturer Defendants' coupons and co-pay assistance programs. All Defendants also suppressed required reporting of adverse addiction events and instances of drug diversion, which would have otherwise influenced third party payor coverage decisions. These associations-in-fact are

referred to as formulary access and coverage enterprises or schemes and are discussed in greater detail, *infra*.

203. The growth in the prescription market for Opioid Drugs was due to the expansion of promoted uses of opioid drugs; namely, for the unsafe and unapproved treatment of chronic pain. For example, according to IMS Health Data, the annual number of OxyContin prescriptions for non-cancer pain increased nearly tenfold between 1997 and 2002, whereas OxyContin prescriptions for cancer pain increased only fourfold during this time.

204. Defendants were thus part of a scheme to dramatically increase the market for the opioid drugs. These efforts were wildly successful. The number of opioid drug prescriptions increased sharply, reaching nearly 250 million prescriptions in 2013, almost enough for every person in the United States to have a bottle of pills. This represents an increase of 300% since 1999. The scheme was so successful that by 2014 the Defendants had turned the opioid drugs into the most prescribed class of drugs in the entire nation, generating a whopping \$11 billion in revenue.

205. During the same time frame, each and every Defendant combined its own respective personnel and financial resources with other defendants and third parties through which Defendants intentionally ignored their legal obligations to identify, monitor, and report suspicious activity indicating drug diversion, and actively concealed evidence of same. These associations-in-fact are referred to as drug diversion concealment enterprises or schemes and are discussed in greater detail, *infra*.

206. For the drug diversion concealment enterprises, each Defendant and its associated participants established and carried out its respective enterprises to accomplish the common goal of protecting the expansion of the opioid drug prescription market and nurturing the expansion of the opioid drug market.

207. The goals and implementation of these five enterprises were intentionally complimentary and mutually reinforcing. The Defendants' respective enterprises, individually and collectively, succeeded in distorting and polluting the discourse surrounding opioid drugs to such a degree that physicians and patients were rendered incapable of making objective and informed decisions concerning the appropriate use of opioid drugs. Likewise, third party payors were prevented from making informed decisions on how and whether to reimburse for the costs of opioid drugs, and whether to continuing doing so.

208. These five Enterprises, the complete nature and extent of which have only recently been revealed to the public and MMO, are explained in greater detail, *infra*.

IV. Defendants' Schemes Expanded the Unsafe and Unapproved "Black Market" for the Opioid Drugs

209. The expansion of the prescription market was only one aspect of the Defendants' deceptive scheme to increase their financial gain. All Defendants intentionally flouted federal regulations, concealing evidence of drug diversion in a concerted effort to nurture the expansion of the market for opioid drugs as well.

210. Though Defendants collected information relating to suspicious prescribing and pharmacy dispensing patterns, they did not (as they were required by law) provide such information to federal or state agencies. Defendants also encouraged others involved in the scheme to conceal this information from regulatory agencies.

211. Defendants' concealment efforts were not merely aimed at the government. Rather, Defendants knew that third party payors would re-evaluate formulary placement for opioid drugs if provided evidence of massive drug diversion. For sales not to plummet, it was thus critical to maintain favorable formulary access. To accomplish that, Defendants could not let third party payors know about the rampant diversion underway.

212. But Defendants did not merely conceal such data. Rather, they shared this information with one another to coordinate micro-targeting opportunities and drive higher sales. In other words, they not only identified where and how the market for opioid drugs flourished, but worked to help such markets thrive and expand, thus creating the engine for “black market” diversion.

213. Defendants even continued to supply opioid drugs to fulfill demand generated by physicians and pharmacies that their own employees had red-flagged as highly suspicious. Employees who were not “on board” with this scheme were pressured to suppress or even change their opinions.

214. Defendants were thus part of a scheme to protect and nurture the market for opioid drugs, which in turn would spin out of control into rampant black market diversion. The drug diversion concealment enterprises are discussed in greater detail, *infra*.

215. The black market for Opioid Drugs expanded greatly as a result of Defendants’ illegal and profit-driven conduct. Much of the data regarding opioid distribution, sales, and consumption is in the hands of Defendants or others. But some publicly available data shows that New York as a whole, and certain parts in particular, consume a number of opioid drug that can be explained only by the diversion of opioids for criminal and non-medically appropriate uses.

V. Manufacturer Defendants Use “Unbranded” Marketing to Evade Laws and Regulations.

216. The Manufacturer Defendants’ enterprises and schemes did not develop by accident. Rather, they were the product of comprehensive marketing and business plans developed for each opioid drug, as well as a concerted effort to change prescriber and physician attitudes about opioids in general. The goals of these plans were simple: to attract new prescribers and increase the overall prescribing of the Manufacturer Defendants’ respective opioid drugs.

217. The Manufacturer Defendants' enterprises and schemes did not develop by accident. Rather, they were the product of comprehensive marketing and business plans developed for each opioid drug, as well as a concerted effort to change prescriber and physician attitudes about opioids in general. The goals of these plans were simple: to attract new prescribes and increase the overall prescribing of the Manufacturer Defendants' respective opioid drugs.

218. From the start, PURDUE promoted OxyContin far beyond the cancer and postsurgical patients. The company aimed to convince doctors to aggressively treat non-cancer pain, and prescribe OxyContin for moderate pain lasting more than a few days. OxyContin ought to be used for bad backs, knee pain, tooth extraction, headaches, fibromyalgia, as well as football, hockey, and dirt-bike injuries, broken bones, and, of course, after surgery. This was a vast new market for an opiate painkiller. U.S. back pain patients alone numbered some thirty-five million people; the total number of cancer patients was a fifth of that.⁷⁸

219. Internal PURDUE documents show that OxyContin was developed to cure its financial problems. In the late 1980s, the patent on its main source of revenue, a morphine pill for cancer patients call MS Contin, was running out. Executives "anticipated a massive loss of revenue as generic versions drove down the price of MS Contin" so a 1990 memo stated that "other controlled-release opioids must be considered."⁷⁹ It certainly worked - the success of OxyContin brought a whole new level of wealth to the Sackler family that owns Purdue. Forbes magazine last year estimated the Sacklers' worth at \$14 billion, which put the family ahead of American dynasties such as the Mellons and Rockefellers.⁸⁰

⁷⁸ S. Quinones, *Dreamland* 126–27 (2015).

⁷⁹ Ryan, Harriet, et al., "‘You want a Description of Hell?’ Oxycontin’s 12-Hour Problem," *The Los Angeles Times*, 5 May 2016. Web. 25 Oct. 2017.

⁸⁰ *Id.*

220. An internal PURDUE document admits that the company did “not want to niche OxyContin just for cancer pain,” so it spent \$207 million on the launch of OxyContin and doubled its sales force to 600.⁸¹

221. CEPHALON promoted its Actiq for migraines, sickle-cell pain, and injuries, although the FDA had approved its use only for cancer pain.⁸² CEPHALON pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay \$425 million.⁸³

222. JANSSEN promoted its Ultracet for everyday chronic pain, distributing posters to doctor’s offices that showed people in active professions with the tagline “*Pain doesn’t fit their schedules.*”⁸⁴

223. ENDO, maker of Opana, Percocet, and Percodan, distributed a patient education publication that said withdrawal symptoms and increased tolerance to opioids are not the same as addiction: “*Addicts take opioids for other reasons, such as unbearable emotional problems.*”⁸⁵

224. Manufacturer Defendants knew that their goal of increasing profits by promoting the prescription of opioids for chronic pain would lead directly to an increase in health care costs for patients, health care insurers, and cities and counties.

225. Marshalling help from consultants and public relations firms, Manufacturer Defendants developed and executed a common strategy to reverse the long-settled understanding of the relative risks and benefits of chronic opioid therapy. Unable to add to the collective body of

⁸¹ *Id.*

⁸² J. Temple, *American Pain* 49 (2015).

⁸³ Press Release, “Biopharmaceutical Company, CEPHALON, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing,” U.S. Dept. of Justice, 29 Sept. 2008, Web. 24 Oct. 2017.

⁸⁴ J. Temple, *American Pain* 49 (2015).

⁸⁵ *Id.*

legitimate medical knowledge concerning the best ways to treat pain and improve patient quality of life, however, Manufacturer Defendants instead sought to distort medical and public perception of existing scientific data.

226. Manufacturer Defendants, collectively and individually, poured vast sums of money into generating articles, CMEs, and other “educational” materials, conducting sales visits to individual doctors, and supporting a network of professional societies and advocacy groups, which was intended to, and which did, create a fake “consensus” supporting the long-term use of opioids.

227. Drug companies’ promotional activities can be branded or unbranded. Unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can evade the extensive regulatory framework governing branded communications because unbranded advertising isn’t regulated by the FDA.⁸⁶

228. Drug companies’ promotional activity can be branded or unbranded. Unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can evade the extensive regulatory framework governing branded communications because unbranded advertising isn’t regulated by the FDA.⁸⁷

229. The federal Food, Drug, and Cosmetic Act (“FDCA”) prohibits the sale in interstate commerce of drugs that are “misbranded.” A drug is “misbranded” if it lacks “adequate directions for use” or if the label is false or misleading “in any particular.”

230. Manufacturer Defendants generally avoided using branded advertisements to

⁸⁶ See, e.g., *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 1836443, 92 UCC Rep. Serv. 2d 729 (N.D. Ill. May 8, 2017) (“Unbranded advertisements do not require FDA review because the FDA considers unbranded advertisements educational rather than promotional”).

⁸⁷ See, e.g., *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 1836443, 92 UCC Rep. Serv. 2d 729 (N.D. Ill. May 8, 2017) (“Unbranded advertisements do not require FDA review because the FDA considers unbranded advertisements educational rather than promotional”).

spread their deceptive messages and claims regarding opioids to evade regulatory review.

231. Instead, Manufacturer Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unregulated, unbranded marketing materials that generally promoted opioid use but did not name a specific opioid while doing so. Through these unbranded materials, Manufacturer Defendants presented information and instructions concerning opioids generally that were false and misleading.

232. By acting through third parties, Manufacturer Defendants could give the false appearance that their messages reflected the views of independent third parties. Later, Manufacturer Defendants cited to these sources as “independent” corroboration of their own statements. Further, as one physician adviser to Manufacturer Defendants noted, third-party documents had not only greater credibility, but also broader distribution, as doctors did not “push back” at having materials, for example, from the non-profit American Pain Foundation (“APF”) on display in their offices, as they would with drug company materials.

233. As part of their marketing scheme, Manufacturer Defendants spread and validated their deceptive messages through the following unbranded scheme (“the Unbranded Scheme”): so-called KOLs (i.e., physicians who influence their peers’ medical practice, including but not limited to prescribing behavior) who wrote favorable journal articles and delivered supportive CMEs; (ii) a body of biased and unsupported, purportedly scientific, literature; (iii) treatment guidelines; (iv) CMEs; and (v) unbranded patient education materials disseminated through groups purporting to be patient-advocacy and Front Groups, which exercised their influence both directly and indirectly through Defendant-controlled KOLs who served in leadership roles in these organizations.

234. Manufacturer Defendants disseminated many of their false, misleading, imbalanced and unsupported messages through the Unbranded Scheme because those messages

appeared to uninformed observers to be independent. Through unbranded materials, Manufacturer Defendants presented information and instructions concerning opioids generally that were false and misleading.

235. Even where such unbranded messages were disseminated through third-parties, Manufacturer Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. Manufacturer Defendants' sales representatives distributed third-party marketing material to their target audiences that was deceptive.

236. Manufacturer Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by third parties, ensuring that Manufacturer Defendants were consistently in control of their content. By funding, directing, editing, and distributing these materials, Manufacturer Defendants exercised control over their deceptive messages and acted in concert with these third parties fraudulently to promote the use of opioids for the treatment of to treat chronic pain.

237. The unbranded marketing materials that Manufacturer Defendants assisted in creating and distributing did not disclose the risks of addiction, abuse, misuse, and overdose, and affirmatively denied or minimized those risks.

238. The warnings on Defendants' own FDA-approved drug labels caution that opioids "expose users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids. Defendants' deceptive unbranded marketing contradicted what they said in their branded materials reviewed by the FDA. For example, ENDO's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy	Opana ER Advertisement
(Unbranded)	(Branded)
"People who take opioids as prescribed usually do not become addicted."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use."

239. In 2007, multiple States sued PURDUE for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited PURDUE from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect and unbranded marketing strategies, however, PURDUE intentionally circumvented these restrictions.

A. Manufacturer Defendants KOLs.

240. After PURDUE launched OxyContin in the U.S. in 1996, the company ran training seminars for KOLs in the pain field. Doctors were invited to all-expenses paid weekends in resort locations like Boca Raton, Florida, and Scottsdale, Arizona. The company found that doctors who attended seminars in 1996 wrote more than twice as many prescriptions as those who didn't, according to a company analysis.⁸⁸ Several thousand of these specialists signed on to the PURDUE "speakers bureau," which paid them to make speeches about opioids at medical conferences and at hospitals.

241. All Manufacturer Defendants cultivated a select circle of doctors chosen and

⁸⁸ Ryan, H. et al., "OxyContin goes Global—'We're only just getting started'," *The Los Angeles Times*, 18 Dec. 2016. Web. 24 Oct. 2017.

sponsored by Manufacturer Defendants solely because they favored the aggressive treatment of chronic pain with opioids. Pro-opioid doctors have been at the hub of Manufacturer Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. These pro-opioid doctors have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of opioid therapy for chronic pain. They have served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and on the boards of purportedly independent pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Manufacturer Defendants were able to exert control of each of these modalities through their KOLs.

242. In return for their pro-opioid advocacy, Manufacturer Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish.

243. Manufacturer Defendants cited and promoted their KOLs and studies or articles by their KOLs to broaden the chronic opioid therapy market. By contrast, Manufacturer Defendants did not support, acknowledge, or disseminate the publications of doctors critical of using chronic opioid therapy.

244. Manufacturer Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of their agenda. Manufacturer Defendants also kept close tabs on the content of the materials published by these KOLs.

245. In their promotion of using opioids to treat chronic pain, Manufacturer Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth, but they continued to publish their misstatements to benefit themselves and Manufacturer Defendants.

B. Manufacturer Defendants' Corrupt Scientific Literature.

246. Rather than test the safety and efficacy of opioids for long-term use, Manufacturer Defendants led physicians, patients, and the public to believe that such tests had already been done. Manufacturer Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to result from independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature was marketing material intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

247. To accomplish their goal, Manufacturer Defendants - sometimes through third-party consultants and/or Front Groups - commissioned, edited, and arranged for the placement of favorable articles in academic journals.

248. Manufacturer Defendants' plans for these materials did not originate in the departments responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in Manufacturer Defendants' marketing departments and with Manufacturer Defendants' marketing and public relations consultants.

249. In these materials, Manufacturer Defendants (or their surrogates) often claimed to rely on "data on file" or presented posters, neither of which are subject to peer review. Still, Manufacturer Defendants presented these materials to the medical community as scientific articles or studies, although Manufacturer Defendants' materials were not based on reliable data and subject to the scrutiny of experts in the field.

250. Manufacturer Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even when Manufacturer Defendants knew that the articles

distorted the significance or meaning of the underlying study.

251. Most notably, PURDUE frequently cited a 1980 item in the well-respected New England Journal of Medicine, J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 (2) New Eng. J. Med. 123 (1980) (“Porter & Jick Letter”), in a manner that makes it appear that the item reported the results of a peer reviewed study. It is also cited in two CME programs sponsored by ENDO.

252. Manufacturer Defendants failed to reveal this “article” is actually a paragraph letter to the editor, not a study, much less a peer-reviewed study. “That single paragraph, buried in the back pages of the *New England Journal of Medicine*, was mentioned, lectured on, and cited until it emerged transformed into, in the words of one textbook, a ‘landmark report’ that ‘did much to counteract’ fears of addiction in pain patients treated with opiates.”⁸⁹

253. The paragraph letter, reproduced in full below, states that the authors only examined their files of hospitalized patients who received opioids.

⁸⁹ S. Quinones, *Dreamland* 108 (2015).

**ADDICTION RARE IN PATIENTS TREATED
WITH NARCOTICS**

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug
Surveillance Program
Boston University Medical Center

Waltham, MA 02154

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. *JAMA*. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. *J Clin Pharmacol*. 1978; 18:180-8.

254. The patients referred to were all treated prior to the letter, which was published in 1980. Because of standards of care prior to 1980, the treatment of those patients with opioids would have been limited to acute or end-of-life situations, not chronic pain. The letter notes that, when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor is there any indication whether the patients were followed after they were discharged from the hospital or, if they were, for how long. None of these serious limitations was disclosed when Manufacturer Defendants and those acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are rarely addictive.

255. Dr. Jick has complained that his letter has been distorted and misused and “does *not* speak to the level of addiction in outpatients who take these drugs for chronic pain.”⁹⁰

256. Manufacturer Defendants worked to not only create and promote favorable studies in the literature, but to discredit or suppress negative information. Manufacturer Defendants' studies

⁹⁰ *Id.* (emphasis in original).

and articles often targeted articles that contradicted Manufacturer Defendants' claims or raised concerns about chronic opioid therapy. To do so, Manufacturer Defendants - often with the help of third-party consultants - used a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

257. Manufacturer Defendants' strategy – to plant and promote supportive literature and then to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted those claims – flatly contradicted their legal obligations. The strategy was intended to, and did, distort prescribing patterns by distorting the truth regarding the risks and benefits of opioids for chronic pain relief.

C. Manufacturer Defendants' Misuse of Treatment Guidelines.

258. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by general practitioners and family doctors targeted by Manufacturer Defendants, who are generally not experts, and who generally have no special training, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and relied on by third-party payors in determining whether they should pay for treatments for specific indications.

1. FSMB

259. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid and pain-specific programs through grants from Manufacturer Defendants.

260. Since 1998, the FSMB has been developing treatment guidelines for using opioids

to treat pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (“1998 Guidelines”) was produced “in collaboration with pharmaceutical companies” and taught not that opioids could be appropriate in limited cases after other treatments had failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option.

261. The same claims made in the 1998 Guidelines, were reiterated in FSMB’s 2004 Model Policy for the Use of Controlled Substances for the Treatment of Pain. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in City of Syracuse.

262. Further, the same claims made in the 1998 Guidelines were made in Dr. Scott Fishman’s, 2007 book, *Responsible Opioid Prescribing*. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers and 163,131 copies were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as the “leading continuing medication (CME) activity for prescribers of opioid medications.”

263. Manufacturer Defendants relied on the 1998 Guidelines to convey the alarming message that “under-treatment of pain” would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB reversed doctors’ fear of discipline, since they used to believe they would be disciplined if their patients became addicted to opioids, however, were now being taught they would be punished if they failed to prescribe opioids to their chronic pain patients.

2. AAPM/APS Guidelines

264. American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) are professional medical societies, each of which received substantial funding from

Manufacturer Defendants from 2009 to 2013. In 1997, AAPM issued a “consensus” statement that Endorsed opioids to treat chronic pain and claimed the risk that patients would become addicted to opioids was low.⁹¹ The Chair of the Committee, Dr. J. David Haddox, was, at the time, a paid speaker for PURDUE. The sole consultant to the committee was Dr. Russell Portenoy. The “consensus” statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM’s website.

265. AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”) and continued to recommend the use of opioids to treat chronic pain. Fourteen of the twenty one panel members who drafted the 2009 Guidelines, including KOLs, Dr. Russell Portenoy, and Dr. Perry Fine, received financial support from Manufacturer Defendants JANSSEN, CEPHALON, ENDO, and PURDUE.

266. Dr. Russell Portenoy, served on the AAPM/APS Guidelines Committees, which Endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation (“APF”), an advocacy organization almost entirely funded by Defendants.

267. Dr. Russell Portenoy, received research support, consulting fees, and honoraria from CEPHALON, ENDO, JANSSEN, and PURDUE (among others), and was a paid consultant to CEPHALON and PURDUE. He was instrumental in opening the door for the regular use of opioids to treat chronic pain.

268. The 2009 Guidelines promote opioids as “safe and effective” for treating chronic pain and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel of deception that influenced

⁹¹ *“The Use of Opioids for the Treatment of Chronic Pain,” American Academy of Pain Medicine & American Pain Society (1997). Web. 25 Oct. 2017.*

not only treating physicians, but also the body of scientific evidence on opioids. They were reprinted in the Journal of Pain, have been cited hundreds of times in academic literature, were, and are, available online and disseminated in City of Syracuse during the relevant time period.

269. Manufacturer Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

3. American Geriatrics Society

270. The American Geriatrics Society ("AGS"), a nonprofit organization serving health care professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter, "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter "2009 AGS Guidelines"). The 2009 AGS Guidelines included the following recommendations: "All patients with moderate to severe pain ... should be considered for opioid therapy (low quality of evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."⁹² These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

271. AGS contracted with Defendants ENDO, PURDUE, and JANSSEN to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. These Defendants were aware of the content of the 2009 Guidelines when they agreed to provide funding for these projects. The 2009 Guidelines were released at the May 2009 AGS Annual Scientific Meeting and first published online on July 2, 2009. AGS submitted grant requests to Defendants including ENDO and PURDUE

⁹² *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331, 1339, 142 (2009), available at http://www.americangeriatrics.org/files/documents/2009_Guideline.pdf

beginning July 15, 2009. Internal AGS discussions in August 2009 reveal that it did not want to receive up-front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed, and allowing these companies to determine whether to provide support only after they have approved the message, AGS ceded significant control to these companies. ENDO, JANSSEN, and PURDUE all agreed to provide support to distribute the guidelines.

272. According to one news report, AGS has received \$344,000 in funding from opioid makers since 2009.⁹³ Five of ten of the experts on the guidelines panel disclosed financial ties to Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants, and investing in Defendants' stock. The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with the companies.

4. Guidelines Not Supported by Manufacturer Defendants

273. The Manufacturer Defendants' guidelines and their influence on patients' treatment varied from the authors of independent guidelines that did not accept a drug company's funding and who reached very different conclusions.

274. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that

⁹³ John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, *Milwaukee J. Sentinel*, May 30, 2012.

the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it.” ASIPP’s Guidelines further advise that “therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain.” ASIPP recommends long-acting opioids in high doses only “in specific circumstances with severe intractable pain” and only when coupled with “continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects.”⁹⁴

275. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the “routine use of opioids in the management of patients with chronic pain,” finding “at least moderate evidence that harms and costs exceed benefits based on limited evidence.”⁹⁵

276. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the U.S. Department of Veterans Affairs (“VA”) and Department of Defense (“DOD”) in 2010, notes the lack of solid evidence-based research on the efficacy of long-term opioid therapy.⁷²

D. Manufacturer Defendants’ Misuse of CMEs.

277. Doctors are required to attend CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations’ conferences, and online, or through written publications. Doctors rely on CMEs not

⁹⁴ Manchikanti, L. et al., “American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment,” 15 *Pain Physician (Special Issue)* S1-S66; Part 2 – Guidance, 15 *Pain Physician (Special Issue)* S67-S116 (2012).

⁹⁵ “Guidelines for the Chronic Use of Opioids,” American College of Occupational and Environmental Medicine (ACOEM), 2011.

only to satisfy licensing requirements, but also to receive information on new developments in medicine or to further their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

278. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Manufacturer Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and especially susceptible to Manufacturer Defendants' deceptions.

279. Manufacturer Defendants sponsored CMEs delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

280. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."⁹⁶

281. Upon information and belief, physicians and other health care providers from City of Syracuse attended or reviewed Manufacturer Defendants' sponsored CMEs during the relevant time period and were misled by them.

⁹⁶ "Opinion 9.0115 - Financial Relationships with Industry in CME, American Medical Association (AMA), Nov. 2011.

282. By sponsoring CME programs put on by Front Groups like APF, AAPM and others, Manufacturer Defendants gained messages favorable to them, as these organizations depended on Manufacturer Defendants for other projects. The sponsoring organizations hired pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Manufacturer Defendants measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

E. Manufacturer Defendants' Misuse of Patient Education Materials and Front Groups.

283. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share ... by bringing awareness to a particular disease that the drug treats."⁹⁷ The United States and New Zealand are the only two developed nations that permit direct-to-consumer marketing.⁹⁸ Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians' willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.⁹⁹ Recognizing this phenomenon, Manufacturer Defendants use relationships with Front Groups to engage in largely unbranded patient education about opioid treatment for chronic pain.

284. Manufacturer Defendants entered into arrangements with numerous Front Groups

⁹⁷ Johar, Kanika, "An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices," 76 Albany L. Rev. 299, 308 (2013).

⁹⁸ "Keeping Watch Over Direct-to-Consumer Ads," U.S. Food & Drug Administration, 16 Oct. 2017. Web. 25 Oct. 2017.

⁹⁹ In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. McKinlay, John B. et al., "Effects of Patient Medication Requests on Physician Prescribing Behavior" Results of a Factorial Experiment," *Med Care*. 2014 Apr; 52(4): 294–299.

to promote opioids. These organizations depend upon Manufacturer Defendants for significant funding and, sometimes, for their survival. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Manufacturer Defendants' marketing in other ways—for example, responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Manufacturer Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain. Manufacturer Defendants funded these Front Groups to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, achieve that goal.

285. Defendants exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure that the Front Groups would generate only the messages Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members, whether it was the patients suffering from pain or doctors treating those patients.

286. Defendants utilized many Front Groups, including many of the same ones. The most prominent are described below, however, there are many others, including, but not limited to, APF, AAPM, APS, AGS, FSMB, American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG"), Pain Care Forum ("PCF"), Alliance for Patient Access ("APA") and American Academy of Integrative Pain Management ("AIPM").

287. These Front Groups, among others utilized by Defendants, advertised and

promoted, and continue to advertise and promote, opioid use generally, but did not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, these Front Groups. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

288. Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain.

289. Due to the close relationship between the Front Groups and the Defendants, the clear lack of independence of the Front Groups - in their finances, management, and mission - and their willingness to allow Defendants to control their activities and messages, support an inference that each Defendant that worked with the Front Groups was able to exercise editorial control over each group's publications.

290. To convince physicians and patients nationally that opioids can and should be used

to treat chronic pain, Defendants used deceptive practices to pursue them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made false claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Defendants have not corrected them, nor have they instructed their Paid Consultant Doctors or Front Groups to correct them, and each continues to spread these deceptions today.

291. To convince physicians and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations reinforced each other and created the dangerously misleading impression that starting patients on opioids was low-risk because most patients would not become addicted; and those who were at greatest risk of addiction could be readily identified and managed; and patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; and the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to mislead and make these false representations today.

1. American Pain Foundation

292. The most prominent of Manufacturer Defendants' Front Groups was APF, which received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012.

293. APF issued purported "education guides" for patients, the news media, and

policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also engaged in a significant multimedia campaign - through radio, television and the internet - to “educate” patients about their “right” to pain treatment with opioids. All of the programs and materials were intended to, and did, reach a national audience, including residents of New York State and City of Syracuse.

294. By 2011, APF depended on incoming grants from Manufacturer Defendants PURDUE, CEPHALON, ENDO, and others. APF board member, Dr. Russell Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.

295. APF held itself out as an independent patient advocacy organization, yet engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing. In reality, APF functioned largely as an advocate for the interests of Manufacturer Defendants, not patients.

296. APF operated in close collaboration with Manufacturer Defendants. APF submitted grant proposals seeking to fund activities and publications suggested by Manufacturer Defendants. APF also assisted in marketing projects for Manufacturer Defendants.

297. The close relationship between APF and Manufacturer Defendants demonstrates APF's clear lack of independence in its finances, management, and mission and its willingness to allow Manufacturer Defendants to control its activities and messages supports an inference that each Manufacturer Defendant that worked with APF could exercise editorial control over its publications.

298. In May 2012, the U.S. Senate Finance Committee investigated APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization “due to irreparable economic circumstances.” APF then “cease[d] to exist, effective

immediately.”¹⁰⁰

2. The American Academy of Pain Medicine

299. AAPM, with the assistance, prompting, involvement, and funding of Manufacturer Defendants, issued improper opioid treatment guidelines and sponsored and hosted CMEs essential to Manufacturer Defendants’ deceptive marketing scheme.

300. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM’s marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an “exclusive venue” for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Manufacturer Defendants ENDO, PURDUE, and CEPHALON were members of the council and presented deceptive programs to doctors who attended this annual event.

301. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids - 37 out of roughly 40 at one conference alone. AAPM’s presidents have included top industry-supported KOLs, Dr. Perry Fine, Dr. Russell Portenoy and Dr. Lynn Webster. Dr. Lynn Webster, was elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are ... small and can be managed.”

¹⁰⁰ Ornstein, Charles et al., “Senate Panel Investigates Drug Companies ties to Pain Groups,” *The Washington Post*, 8 May 2012. Web. 25 Oct. 2017.

302. AAPM's staff understood that they and their industry funders were engaged in a common task. Manufacturer Defendants could influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

F. Defendants' Target Valuable and Lucrative Populations

1. The Elderly

303. Elderly patients taking opioids have been found to suffer elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression, which, as Defendants acknowledge in their labels (but not in their marketing), occurs more frequently in elderly patients. A 2010 paper in the Archives of Internal Medicine reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks and strokes than users of NSAIDs. Defendants' targeted marketing to the elderly and the absence of cautionary language in their promotional materials flies in the face of scientific evidence and their own labels and creates a heightened risk of serious injury to elderly patients.

304. Defendants promoted the notion - also without adequate scientific foundation - that the elderly are particularly unlikely to become addicted to opioids. AGS's 2009 Guidelines, for example, which PURDUE, ENDO, and JANSSEN publicized, described the risk of addiction as "exceedingly low in older patients with no current or past history of substance abuse." Yet, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

305. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59. In New York State and in City of Syracuse, use of chronic opioid therapy by elderly patients is significant. Many senior citizens start on opioids to treat chronic back pain or arthritis.

2. Veterans

306. Veterans are also suffering greatly from the effects of Defendants' targeted marketing. A 2008 survey showed prescription drug abuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills - four times as many as they did in 2001. Further, one-third of veterans prescribed opioids as of 2012 remained on take-home opioids for more than 90 days. Although many of these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment. Among former service members receiving VA services nationally in a single year (2005), 1,013 had died of accidental drug overdoses-double the rate of the civilian population.

307. According to a study published in the 2013 Journal of American Medicine, veterans returning from Iraq and Afghanistan who were prescribed opioids had a higher incidence of adverse clinical outcomes, like overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death. Yet, in 2014, according to a VA Office of Inspector General ("OIG") Report, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines, such as Xanax or Valium – a mix “strongly associated with death from opioid overdose.” Again, as with elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and omitted from their promotional materials the known, serious risks opioids posed to them.

308. *Exit Wounds*, a 2009 publication sponsored by PURDUE, distributed by APF with grants from JANSSEN and ENDO, and written as a personal narrative of one veteran, describes opioids as "underused" and the "gold standard of pain medications" and fails to disclose the risk of

addiction, overdose, or injury. It notes that opioid medications “increase a person's level of functioning” and, that “[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications.” The book also asserts that “[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards.” As laid out above, the FSMB itself received support from Defendants during the time it created and published its guidelines.

309. *Exit Wounds* minimizes the risks from chronic opioid therapy and does not disclose the risk that opioids may cause fatal interactions with benzodiazapines, which were taken by a significant number of veterans.¹⁰¹ It is not the unbiased narrative of a returning war veteran. It is pure marketing, sponsored by PURDUE, ENDO, and JANSSEN. Yet, JANSSEN, for example, supported the marketing effort, and its insufficient disclosures, despite acknowledging on the label for its opioid Duragesic that its use with benzodiazepines “may cause respiratory depression, hypotension, and profound sedation or potentially result in coma.” A similar warning is found on the labels of other Defendants' opioids.

310. The deceptive nature of *Exit Wounds* is obvious in comparing it to guidance on opioids published by the VA and DOD in 2010 and 2011. The VA's *Taking Opioids Responsibly* describes opioids as “dangerous.” It cautions against taking extra doses and mentions the risk of overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects and death - none of which is disclosed in *Exit Wounds*.

¹⁰¹ FDA Guidance states that the materials designed to target a particular audience should disclose risks particular to that audience. See FDA, Guidance for Industry, “Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs,” August 6, 2015.

VI. Manufacturer Defendants acted through and with the same network of Front Groups in the Creation, Promotion, and Control of Unbranded Marketing

311. Like cigarette makers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Manufacturer Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superiority of opioids to treat chronic pain.

312. Manufacturer Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the same language and format to disseminate the same deceptive messages regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were disseminated nationwide, including to New York State and City of Syracuse prescribers and patients.

313. One vehicle for Manufacturer Defendants' marketing collaboration was Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

314. PCF comprises representatives from opioid manufacturers and distributors (including CEPHALON, ENDO, JANSSEN, and PURDUE); doctors and nurses in the field of pain care; professional organizations, including AAPM, APS, and American Society of Pain Educators; patient advocacy groups, including APF and ACPA; and other similar organizations, almost all of which received substantial funding from Manufacturer Defendants.

315. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated

in 2009 to communicate the risks of opioids to prescribers and patients.¹⁰² This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would undermine Manufacturer Defendants' marketing efforts.

316. The recommendations claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." Manufacturer Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, not undermine, their deceptive marketing of opioids for chronic pain.

VII. Manufacturer Defendants' Misrepresentations.

317. Manufacturer Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects, caused deceptive materials and information to be placed into the marketplace, including to prescribers, patients, and payors in New York State and City of Syracuse. These promotional messages were intended to and encouraged patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

318. Doctors are the gatekeepers for all prescription drugs so, not surprisingly, Manufacturer Defendants focused the bulk of their marketing efforts, and their multi-million-dollar budgets, on the professional medical community. Particularly because of barriers to prescribing opioids, which are regulated as controlled substances, Manufacturer Defendants knew doctors would not treat patients with common chronic pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks. Accordingly, Manufacturer Defendants did not disclose to prescribers, patients or the public that evidence to support their promotional claims was

¹⁰² The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

inconclusive, non-existent or unavailable. Rather, each Manufacturer Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. As a result, New York State and City of Syracuse doctors prescribed opioids long-term to treat chronic pain - something that most of them never would have considered prior to Manufacturer Defendants' campaign.

319. A Drug company's marketing materially impacts doctors' prescribing behavior.¹⁰³ Doctors rely on drug companies to provide them with truthful information about the risks and benefits of their products, and they are influenced by their patients' requests for particular drugs.

320. Manufacturer Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.¹⁰⁴ These results are directly due to Manufacturer Defendants' fraudulent marketing campaign.

321. Manufacturer Defendants:

- a. misrepresented the truth about how opioids lead to addiction;
- b. misrepresented that opioids improve function;

¹⁰³ See, e.g., Manchanda, P. & Chintagunta, P.K. *Marketing Letters* (2004) 15: 129; Larken, Ian et al., "Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children," *Health Affairs* 33, no.6 (2014):1014-1023 (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs). See also Van Zee, Art, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy," *American Journal of Public Health* 99.2 (2009): 221-227. PMC. (noting an increase of OxyContin prescriptions from 670,000 annually in 1997 to about 6.2 million in 2002 and an approximate doubling of Purdue's internal sales force from 1996 to 2000.)

¹⁰⁴ Hwang, Catherine S. et al., "Prescription Drug Abuse A National Survey of Primary Care Physicians.," *JAMA Intern Med.* 2015;175(2):302-304.

- c. misrepresented that addiction risk can be managed;
- d. misled doctors, patients, and payors through misleading terms like pseudoaddiction;
- e. falsely claimed that opioid withdrawal is simply managed;
- f. misrepresented that increased doses pose no significant additional risks;
- g. falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

322. Underlying each of Manufacturer Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Manufacturer Defendants' collective effort to hide from the medical community the fact that there exist no adequate and well-controlled studies of opioid use longer than 12 weeks.¹⁰⁵

A. Manufacturer Defendants Misrepresented How Opioids Lead To Addiction.

323. Manufacturer Defendants' fraudulent representation that opioids are rarely addictive is central to Manufacturer Defendants' scheme. Through their well-funded, comprehensive, aggressive marketing efforts, Manufacturer Defendants succeeded in changing the perceptions of many physicians, patients, and health care payors and in getting them to accept that addiction rates are low and that addiction is unlikely to develop when opioids are prescribed for pain. That, in turn, directly led to the expected, intended, and foreseeable result that doctors prescribed more opioids to more patients – thereby enriching Manufacturer Defendants.

324. Acting directly or through and with third parties, each of the Manufacturer Defendants claimed that the potential for addiction even from long term use of its drugs was relatively small, or non-existent, even though that was false and there was no scientific evidence to support their claim.

¹⁰⁵ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013).

325. For example, PURDUE sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids would become addicted.¹⁰⁶ This publication also falsely asserted that pain is undertreated due to "misconceptions about opioid addiction."

326. PURDUE published a prescriber and law enforcement pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which under the heading, "*Indications of Possible Drug Abuse*," shows pictures of the stigmata of injecting or snorting opioids – skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use.¹⁰⁷ Thus, these misrepresentations wrongly reassure doctors that as long as they do not observe those signs, they need not worry about their patients abusing or becoming addicted to opioids.

327. For another example, in the 1990s, PURDUE amplified the pro-opioid message with promotional videos and featuring Dr. Russell Portenoy and other doctors, which claimed, "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."¹⁰⁸

328. PURDUE's sales representatives told New York State and City of Syracuse prescribers that its drugs were "steady state", the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused than other

¹⁰⁶ In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain.

¹⁰⁷ Purdue itself submitted briefing materials in October 2010 to a meeting of the FDA's Joint Meeting of Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee in which it stated that OxyContin was used non-medically by injection 4-17% of the time.

¹⁰⁸ Excerpts from one such video, including the statement quoted here, may be viewed at "Thousands Die Annually from Pain Med Overdose," *The Wall Street Journal*, 14 Dec. 2012, <http://www.wsj.com/video/thousands-die-annually-from-pain-med-overdose/6E7C0A5F-48F5-47CE-9A0E-64439EF7A5AB.html>.

opioids.

329. PURDUE's sales representatives told New York State and City of Syracuse prescribers that Butrans has a lower abuse potential than other drugs because it was essentially tamper proof and, after a certain point, patients no longer experience a "buzz" from increased dosage.

330. Advertisements that PURDUE sent to New York State and City of Syracuse prescribers stated that Oxycontin ER was less likely to be favored by addicts, and, therefore, less likely to be abused or diverted, or result in addiction.

331. PURDUE, JANSSEN and ENDO contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids and the claim is untrue. PURDUE was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.

332. CEPHALON sponsored and facilitated the development of a guidebook, *Opioid Medication and REMS: A Patient's Guide*, which claims, among other things, that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."

333. For example, CEPHALON and PURDUE sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioids from multiple sources, or theft.

334. For another example, PURDUE sponsored and JANSSEN and ENDO provided

grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught, “[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications”. Although the term “unlikely” is not defined, the overall presentation suggests that the risks is so low as not to be a worry.

335. For another example, JANSSEN sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA and APF, which described as a “myth” the fact that opioids are addictive and asserts as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” Although the term “rarely” is not defined, the overall presentation suggests that the risk is so low as not to be a worry. The language also implies that as long as a prescription is given, opioid use is not a problem.

336. JANSSEN currently runs a website, *Prescriberesponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”

337. JANSSEN’s sales representatives told New York State and City of Syracuse prescribers that Nucynta’s unique properties eliminated the risk of addiction associated with the drug.

338. ENDO’s advertisements for the 2012 reformulation of Opana ER claimed it was designed to be crush resistant, in an attempt to convey that it was less likely to be abused. This claim was false and the FDA warned in a May 10, 2013 letter that there was no evidence ENDO’s design “would provide a reduction in oral, intranasal or intravenous abuse” and ENDO’s “post marketing date submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse.” Further, ENDO instructed its sales representatives to repeat this claim about the “design”, with the intention of conveying Opana ER was less subject to abuse.

339. ENDO sponsored a website, *painknowledge.com*, through APF, which claimed

that: “[p]eople who take opioids as prescribed usually do not become addicted.” Although the term “usually” is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that as long as a prescription is given, opioid use will not become problematic. The website also contained a flyer called “*Pain: Opioid Therapy*.” This publication included a list of adverse effects that omitted significant adverse effects including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. The website also claimed in 2009 that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life and “improved function” as benefits of opioid therapy.

340. ENDO sponsored a website, *Painaction.com*, which stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” For another example, PURDUE sponsored, and JANSSEN provided grants to, APF to distribute *Exit Wounds* (2009) to veterans, which taught, “[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications”.

341. ENDO sponsored a CME published by APF’s National Initiative on Pain Control (NIPC), entitled *Persistent Pain in the Older Adult*. These CMEs claimed that opioids used by the elderly patients present “possibly less potential for abuse than in younger patients”, which lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients.

342. For another example, ENDO distributed a patient education pamphlet edited by Dr. Russell Portenoy, entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that “[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems.” This implies that patients prescribed opioids for genuine pain will not become addicted,

which is unsupported and untrue.

343. ENDO's sales representatives told New York State and City of Syracuse prescribers that its drugs were "steady state", the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused than other opioids.

344. ACTAVIS' predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on ACTAVIS' acquisition of its predecessor's marketing materials along with the rights to Kadian, ACTAVIS continued to use this brochure in 2009 and beyond. Although the term "less likely" is not defined, the overall presentation suggests the risk is so low as not to be a worry.

345. The guide states as a "fact" that "Many studies" show that opioids are rarely addictive when used for chronic pain. No such studies exist.

346. Documents from a 2010 sales training indicate that ACTAVIS trained its sales force that long-acting opioids were less likely to produce addiction than short-acting opioids, although there is no evidence that either form of opioid is less addictive or that any opioids can be taken long term without the risk of addiction.

347. ACTAVIS' Kadian sales representatives told New York State and City of Syracuse prescribers that Kadian was "steady state" and had extended release mechanisms, the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused than other opioids.

348. In discussions with New York State and City of Syracuse prescribers, PURDUE's CEPHALON's, JANSSEN's, DEPOMEDS's, ENDO's, MALLINCKRODT's, ACTAVIS', and/or

INSYS’ sales representatives failed to and/or omitted the addiction risks related to their respective drugs. The Individual Defendants also failed to and/or omitted the addiction risks related to opioid drugs.

349. Rather than honestly disclose the risk of addiction, Manufacturer Defendants attempted to portray those who were concerned about addiction as callously denying treatment to suffering patients. To increase pressure on doctors to prescribe chronic opioid therapy, Manufacturer Defendants turned the tables: they suggested that doctors who failed to treat their patients’ chronic pains with opioids were failing their patients and risking professional discipline, while doctors who relieved their patients’ pain using long-term opioid therapy were following the compassionate (and professionally less risky) approach. Manufacturer Defendants claimed that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-regulated and under-prescribed. The Treatment Options guide funded by PURDUE and CEPHALON states “[d]espite the great benefits of opioids, they are often underused.” The APF publication funded by PURDUE, *A Policymaker’s Guide to Understanding Pain & Its Management*, laments that: “Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include . . . misconceptions about opioid addiction.”¹⁰⁹

350. *Let’s Talk Pain*, sponsored by APF, AAPM and JANSSEN, likewise warns, “strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence.” The program says, “[b]ecause of the potential for abusive and/or addictive behavior, many health care professionals have been reluctant to prescribe opioids for their patients.... This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United

¹⁰⁹ This claim also appeared in a 2009 publication by APF, *A Reporter’s Guide*.

States.”

351. The Joint Commission even published a guide sponsored by PURDUE on pain management that stated “[s]ome clinicians have inaccurate and exaggerated concerns about addiction, tolerance and risk of death. This attitude prevails despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”¹¹⁰

352. Detailers for PURDUE, CEPHALON, JANSSEN, DEPOMED, ENDO, MALLINCKRODT, ACTAVIS and/or INSYS in the State of New York minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above. The Individual Defendants also misrepresented the potential for abuse of opioids as set forth herein, and routinely did not correct misrepresentations as noted herein.

353. All of these claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC *Guideline for Prescribing Opioids for Chronic Pain – United State 2016*¹¹¹, Endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The *Guideline* points out that “[o]pioid pain medication use presents serious risks, including ... opioid use disorder” and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”

354. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for intermediate

¹¹⁰ Hirsch, Ronald, “The Opioid Epidemic: It’s Time to Place Blame Where It Belongs,” *Observer.com*, 23 May 2016. Web. 25 Oct. 2017.

¹¹¹ 2016 CDC *Guideline for Prescribing Opioids for Chronic Pain – United State 2016*, <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>

release (“IR”) opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

B. Manufacturer Defendants Misrepresent That Opioids Improve Function.

355. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants also had to persuade them that there was a significant upside to long-term opioid use.

356. Manufacturer Defendants produced, sponsored, or controlled materials with the expectation that, by instructing patients and prescribers that opioids would improve patient functioning and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy for patients in the belief that lack of improvement in quality of life could be alleviated by increasing doses or prescribing supplemental short-acting opioids to take as-needed for breakthrough pain.

357. Research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable

to work.¹¹² Despite this lack of evidence of improved function, and the existence of evidence to the contrary, Manufacturer Defendants consistently promoted opioids as capable of improving patients' function and quality of life without disclosing the lack of evidence for this claim.

358. Claims that opioids improve patients' function are misleading because such claims have "not been demonstrated by substantial evidence or substantial clinical experience."¹¹³

359. The Federation of State Medical Boards' Responsible Opioid Prescribing (2007), sponsored by drug companies including CEPHALON, ENDO and PURDUE, taught that relief of pain itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function."

360. PURDUE sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients," with the implication these studies presented claims of long-term improvement. This guide was originally published in 2011 and is still available on line today.

361. To the contrary, the sole reference for the functional improvement claim (i) noted the absence of long- term studies and (ii) stated, "For functional outcomes, the other analgesics were significantly more effective than were opioids."

362. PURDUE ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that

¹¹² Dersh, Jeffrey et al., "Prescription Opioid Dependence is Associated with Poorer Outcomes in Disabling Spinal Disorders," *Spine (Phila Pa 1976)*. 2008 Sep 15; 33(20):2219-27.

¹¹³ Letter from Thomas W. Abrams, RPh., MBA, Dir., Div. of Marketing, Advertising and Communications to Brian A. Markison, Chairman, King Pharmaceuticals, Re: NDA 21-260 (March 24, 2008).

OxyContin improves patients' function.

363. PURDUE, JANSSEN and ENDO sponsored and/or provided grants to APF for the distribution of *Exit Wounds* (2009), which taught veterans that opioid medications “increase your level of functioning.” *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans with post-traumatic stress disorder.

364. PURDUE and CEPHALON sponsored the APF’s *Treatment Options: A Guide for People Living with Pain* taught patients that opioids, when used properly “give [pain patients] a quality of life we deserve.” The Treatment Options guide notes that non-steroidal anti-inflammatory drugs (e.g., Aspirin or Ibuprofen) have greater risks with prolonged duration of use, but there was no similar warning for opioids. The APF distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report, and was available online until APF shut its doors in 2012.

365. PURDUE, CEPHALON and ENDO sponsored and/or distributed *Responsible Opioid Prescribing* (2007), which taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

366. CEPHALON sponsored a CME written by KOL, Dr. Lynn Webster, titled “*Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that CEPHALON’s Actiq and Fentora improve patients’ quality of life and allow for more activities when taken in conjunction with long-acting opioids.

367. JANSSEN sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* with the AAPM, ACPA and APF. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids like sleeping

through the night, returning to work, recreation, sex, walking, and climbing stairs. This guide states as a “fact” that “opioids may make it *easier* for people to live normally” (emphasis in the original). The myth/fact structure implies authoritative support for the claim that does not exist. Targeting older adults also ignored heightened opioid risks in this population.

368. JANSSEN sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by JANSSEN claiming that opioids allowed a patient to “continue to function.” This video is still available today on YouTube.

369. The website *Let's Talk Pain* in 2009 featured a video interview, which was edited by JANSSEN personnel, claiming that opioids were what allowed a patient to “continue to function,” falsely implying that her experience would be representative.

370. ENDO distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

371. ENDO's NIPC website *painknowledge.com* claimed in 2009 that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life (as well as “improved function”) as benefits of opioid therapy. The grant request that ENDO approved for this project specifically indicated NIPC's intent to make misleading claims about function, and ENDO closely tracked visits to the site.

372. ENDO was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” The CME was

disseminated via webcast.

373. ACTAVIS distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives. In 2010, the FDA warned ACTAVIS, in response to its advertising described in paragraph 40, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."¹¹⁴

374. Documents from a 2010 sales training indicate that ACTAVIS trained its sales force to instruct prescribers that "most chronic benign patients do have **markedly improved ability to function** when maintained on chronic opioid therapy." Further, ACTAVIS training materials from 2010 also show that they trained their sales force that increasing and restoring function is an expected outcome of chronic Kadian therapy, including physical, social, vocational, and recreational function.

375. PURDUE's, CEPHALON's, JANSSEN's, DEPOMED's, ENDO's, MALLINCKRODT's, ACTAVIS' and/or INSYS' sales representatives conveyed, and continue to convey to New York State, Onondaga County and/or City of Syracuse prescribers, the message that opioids will improve patients' ability to function and improve their quality of life by helping them to become more physically active and return to work. The Individual Defendants also

¹¹⁴ Warning Letter from Thomas Abrams, Dir. FDA Div. of Mktg, Adver., & Commc'ns, to Doug Boothe, CEO, ACTAVIS Elizabeth, LLC (Feb. 18, 2010) available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeViolationLettertoPharmaceuticalCompanies/ucm259240.htm>.

spread messages that opioids will improve patient's ability to function and improve their quality of life as set forth herein.

376. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline¹¹⁵ approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and ... complete relief of pain is unlikely."

377. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

378. The 2016 CDC Guideline¹¹⁶ was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life.

C. Manufacturer Defendants Misrepresent That Addiction Risk Can Be Effectively Managed

379. Manufacturer Defendants each continue to maintain to this day that most patients safely can take opioids long-term for chronic pain without becoming addicted. Presumably to explain why doctors encounter so many patients addicted to opioids, Manufacturer Defendants admit that some patients could become addicted, but that doctors can avoid or manage that risk by using screening tools or questionnaires. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) so doctors can more closely monitor patients at greater risk of addiction.

380. There are three fundamental flaws in Manufacturer Defendants' representations

¹¹⁵ 2016 CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016, <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>

¹¹⁶ *Id.*

that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Even if the tools are effective, they may not always be applied correctly, and are subject to manipulation by patients. Second, there is no reliable scientific evidence that high-risk or addicted patients identified through screening can take opioids long-term without triggering or worsening addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients not identified through such screening can take opioids long-term without significant danger of addiction.

381. Addiction is difficult to predict on a patient-by-patient basis. An Evidence Report by the Agency for Healthcare Research and Quality (“AHRQ”), which “systematically review[ed] the current evidence on long-term opioid therapy for chronic pain” identified “[n]o study” that had “evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse.”¹¹⁷ Furthermore, doctors were misled to attempt to treat high-risk patients, who have a documented predisposition to substance abuse, by resorting to patient contracts, more frequent refills, or urine drug screening, which has not proven to work in the real world.¹¹⁸

382. Manufacturer Defendants’ misrepresentations regarding the risk of addiction from

¹¹⁷ *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services, Evidence Report/Technology Assessment No. 218, ES-2, ES-21, Sep. 2014.

¹¹⁸ See Von Korff, Michael et al., “Long-Term Opioid Therapy Reconsidered,” *Ann Intern Med.* 2011 Sep 6; 155(5): 325–328; Manchikanti, L. et al., “American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment,” *15 Pain Physician (Special Issue)* S1-S66; Part 2 – Guidance, *15 Pain Physician (Special Issue)* S67-S116 (2012).

chronic opioid therapy were particularly dangerous because they were aimed at general practitioners or family doctors, who treat many chronic conditions but lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. One study conducted by pharmacy benefits manager Express Scripts concluded, after analyzing 2011–2012 narcotic prescription data of the type regularly used by Manufacturer Defendants to market their drugs, that, of the more than half million prescribers of opioids during that time period, only 385 were identified as pain specialists.¹¹⁹

383. In materials they produced, sponsored, or controlled, Manufacturer Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting on opioid therapy for chronic pain. Manufacturer Defendants' marketing scheme contemplated a "heads we win; tails we win" outcome: patients deemed low risk were to receive opioids on a long-term basis without enhanced monitoring, while and patients deemed high risk were also to receive opioids on a long-term basis but with more frequent visits, tests and monitoring.

384. The Manufacturer Defendants each claimed that the risk of addiction could be avoided or managed, which claims were deceptive and without scientific support.

385. PURDUE sponsored a 2011 webinar taught by Dr. Lynn Webster, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach New York doctors. Dr. Lynn Webster, also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as

¹¹⁹ "Identifying High Prescribers," *Lab.express-scripts.com, Express Scripts*, 9 June 2014. Web. 25 Oct. 2017.

indications of undertreated pain. In Dr. Lynn Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids.

386. PURDUE sponsored a 2012 CME program taught in San Diego, California, by Steven P. Stanos, DO, a Chicago based KOL, titled *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high risk patient showing signs of potentially addictive behavior.

387. PURDUE's unbranded website, *In the Face of Pain* (inthefaceofpain.com) states that the policies that "restrict access to patients with pain who also have a history of substance abuse" and "requiring special government issued prescription forms for the only medications that are capable of relieving pain that is severe" are "at odds with" best medical practices.¹²⁰

388. As recently as 2015, PURDUE has represented in scientific conferences that "bad apple" patients - and not opioids - are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

389. APF's *Treatment Options: A Guide for People Living with Pain*, sponsored by PURDUE and CEPHALON, falsely reassured patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."

390. ENDO paid for a 2007 supplement available for continuing education credit in the Journal of Family Practice written by a doctor who became a member of ENDO's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* created by Dr. Lynn Webster, and linked to JANSSEN or (b) the *Screening and Opioid Assessment for Patients with Pain*,

¹²⁰ See *In the Face of Pain Fact Sheet: Protecting Access to Pain treatment*, Purdue Pharma, L.P.
<http://www.inthefaceofpain.com/content/uploads/2011/12/>.

and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts.

391. Documents from a 2010 sales training indicate that ACTAVIS trained its sales force that prescribers can use risk screening tools to limit the development of addiction.

392. PURDUE’s, CEPHALON’s, JANSSEN’s, DEPOMED’s, ENDO’s, MALLINCKRODT’s, ACTAVIS’ and/or INSYS’ sales representatives told New York State, Onondaga County and/or City of Syracuse prescribers, that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction. The Individual Defendants also spread messages that screening tools could be used to manage the risks of addiction as set forth herein.

393. Dr. Lynn Webster was the co-founder and Chief Medical Director of Lifetree Clinical Research an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster, was President in 2013 and is, or was, a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published ENDO’s special advertising supplements touting Opana ER. Dr. Lynn Webster was the author of numerous CMEs sponsored by CEPHALON, ENDO, and PURDUE. At the same time, Dr. Webster, was receiving significant funding from Defendants (including nearly \$2 million from CEPHALON). Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become

addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Lynn Webster's Opioid Risk Tool appear on, or are linked to, websites run by ENDO, JANSSEN, and PURDUE. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response." ENDO distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."¹²¹

394. Dr. Russell Portenoy made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast in New York and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."

395. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the

¹²¹ John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, *Milwaukee Wisc. J. Sentinel* (2/19/12).

effectiveness of opioids does not exist." Dr. Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, ... I guess I did."¹²²

396. The 2016 CDC Guideline confirms the falsity of these misrepresentations. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies - such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse - "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."¹²³

D. Manufacturer Defendants Mislead With Use Of Purportedly Scientific Terms Like "Pseudoaddiction."

397. Manufacturer Defendants instructed patients and prescribers that signs of addiction are actually the product of untreated pain, thereby causing doctors to prescribe ever more opioids despite signs that the patient was addicted. The word "pseudoaddiction" was concocted by Dr. J. David Haddox, who later went to work for PURDUE, and was popularized in opioid therapy for chronic pain by Dr. Portenoy, who consulted for Manufacturer Defendants CEPHALON, ENDO, JANSSEN, and PURDUE. Much of the same language appears in other Manufacturer Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction"—as if patients could not experience both.

398. In the materials they produced, sponsored, or controlled, Manufacturer Defendants

¹²² Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec 17, 2012.

¹²³ 2016 CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016, <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>

and/or the Individual Defendants misrepresented that the concept of “pseudoaddiction” is substantiated by scientific evidence.

399. The Manufacturer Defendants in their publications and statements, as set forth below, falsely state or suggest that the concept of “pseudoaddiction” is substantiated by scientific evidence and accurately describes the condition of the patients who only need, and should be treated with, more opioids.

400. FSMB’s Responsible Opioid Prescribing (2007), sponsored by CEPHALON and PURDUE, and distributed by CEPHALON, PURDUE and ENDO, taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all really signs of “pseudoaddiction”, rather than true addiction. Responsible Opioid Prescribing remains for sale online. PURDUE also spent over \$100,000 to support the distribution of the book. CEPHALON spent \$150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists. ENDO spent \$246,620 to buy copies of this book, which was distributed by their sales force. The 2012 edition, which also remains available online, continues to teach that “pseudoaddiction” is a real concept.

401. PURDUE did not mention that the author who concocted both the word and the phenomenon it purported to describe became a PURDUE Vice President; nor did PURDUE disclose the lack of scientific evidence to support the existence of “pseudoaddiction.”¹²⁴

402. PURDUE posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, *PartnersAgainstPain.com*, in 2005, and circulated this pamphlet after 2007. The pamphlet listed conduct including “illicit drug use and deception” that it

124 Weissman, DE & Haddox, JD, “Opioid Pseudoaddiction-an Iatrogenic Syndrome,” *Pain*. 1989 Mar; 36(3):363-6.

claimed was not evidence of true addiction but was indicative of “pseudoaddiction” caused by untreated pain. It also stated, “Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is untreated... Even such behaviors as illicit drug use and deception can occur in the patient’s efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.”

403. PURDUE published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described “pseudoaddiction” as a concept that “emerged in the literature” to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated.

404. PURDUE sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of “pseudoaddiction,” the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long acting opioid.

405. PURDUE sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which states: “Pseudoaddiction describes patient behaviors that may occur **when pain is undertreated** ... Pseudoaddiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated.” (Emphasis added).

406. JANSSEN sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: “pseudoaddiction... refers to patient behaviors that may occur when pain is under-treated... Pseudoaddiction is different from true addiction because such behaviors can be resolved

with effective pain management." (Emphasis added).

407. ENDO sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted "pseudoaddiction" by teaching that a patient's aberrant behavior was the result of untreated pain. ENDO substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

408. ENDO also distributed copies of a book by KOL Dr. Lynn Webster, entitled *Avoiding Opioid Abuse While Managing Pain* (2007). ENDO's internal planning documents describe the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that when faced with signs of aberrant behavior, the doctor should regard it as pseudoaddiction and thus, increasing the dose in most cases... should be the clinician's first response." (Emphasis added).

409. Documents from a 2010 sales training that ACTAVIS used to train its sales force to instruct physicians that aberrant behaviors like self-escalation of doses constituted "pseudoaddiction".

410. The 2016 CDC Guideline¹²⁵ rejects the concept of "pseudoaddiction". The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

125 2016 CDC Guideline for Prescribing Opioids for Chronic Pain – United State 2016, <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>

411. Even one of the Defendants has effectively repudiated the concept of “pseudoaddiction”. In finding that “[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents,” the State of New York, in its 2016 settlement with ENDO, replied that “Endo’s Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the ‘pseudoaddiction’ concept’ and acknowledged the difficulty in distinguishing “between addiction and ‘pseudoaddiction’.” Consistent with this, ENDO agreed not to “use the term ‘pseudoaddiction’ in any training or marketing” in New York. ENDO, remained free to do so in other states.

E. Manufacturer Defendants Claim Withdrawal Is Easily Managed.

412. To underplay the risk and impact of addiction, Manufacturer Defendants claimed that, while patients become physically “dependent” on opioids, physical dependence is not the same as addiction and can be addressed, if and when pain relief is no longer desired, by gradually tapering patients’ dosage to avoid the adverse effects of withdrawal. Manufacturer Defendants fail to disclose the difficult and painful effects that patients can experience when removed from opioids – an adverse effect that also makes it less likely that patients can stop using the drugs.

413. Defendants deceptively minimized the significant symptoms of opioid withdrawal-which, as explained in the 2016 CDC Guideline¹²⁶, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction- and grossly understated the difficulty oftapering, particularly after long-term opioid use.

414. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the

¹²⁶ *Id.*

dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to pause and restart tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

415. In materials Manufacturer Defendants produced, sponsored, and controlled, Manufacturer Defendants made misrepresentations to persuade doctors and patients that withdrawal from their opioids was not a problem and they should not be hesitant about prescribing or using opioids. These claims were not supported by scientific evidence.

416. The Manufacturer Defendants each made statements and published materials, as set forth below, that falsely state or suggest that withdrawal from opioids was not a problem and they should not be hesitant about prescribing or using opioids.

417. PURDUE sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

418. PURDUE sales representatives told New York State and City of Syracuse prescribers that the effects of withdrawal from opioid use can be successfully managed.

419. PURDUE's sales representatives told New York State and City of Syracuse prescribers that the potential for withdrawal on Butrans was low due to its low potency and its extended release mechanism.

420. A JANSSEN Power Point presentation used for training its sales representatives titled "Selling Nucynta ER" indicates that the "low incidence of withdrawal symptoms" is a "core message" for its sales force. This message is repeated in numerous JANSSEN training materials from 2009-2011. The studies supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long term and at high doses will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Jansen relied upon a study that only began tracking withdrawal symptoms in patients 2 to 4 days after discontinuing opiate use, when Jansen knew, or should have known, that these symptoms peak earlier than that for most patients. Relying on data after that initial window painted a misleading picture of the likelihood and severity of withdrawal associated with chronic opioid therapy. JANSSEN also knew, or should have known, that the patients involved in the study were not on the drug long enough to develop rates of withdrawal symptoms comparable to rates of withdrawal suffered by patients who use opiates for chronic pain – the use for which Jansen promoted Nucynta ER.

421. Jansen's sales representatives also told New York State and City of Syracuse prescribers that patients on JANSSEN's drugs were less susceptible to withdrawal than those on other opioids.

422. A CME sponsored by ENDO entitled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering a patient's opioid dose by 10% to 20%

per day for ten days. This claim was misleading because withdrawal in a patient already physically dependent would take longer than ten days – when it succeeds at all.¹²⁷

423. Documents from a 2010 sales training indicate that ACTAVIS trained its sales force that discontinuing opioid therapy can be handled “simply” and that it can be done at home. ACTAVIS’ sales representatives training claimed opioid withdrawal would take only one week, even in addicted patients.

424. PURDUE's, CEPHALON's, JANSSEN's, DEPOMED's, ENDO's, MALLINCKRODT's, ACTAVIS', and/or INSYS' sales representatives told New York State, Onondaga County and/or City of Syracuse prescribers that their drugs were less susceptible to withdrawal than those on other opioids. The Individual Defendants spread messages that withdrawal symptoms from opioids could be easily managed.

F. Manufacturer Defendants Misrepresent Increased Doses Pose No Significant Additional Risks.

425. Manufacturer Defendants falsely claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were “frighteningly high,” suggesting that patients would eventually reach a stable, effective dose. Each of Manufacturer Defendants’ claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses.

426. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief.

¹²⁷ See Ballantyne, Jane C. et al., “New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain With Opioids,” *Intl. Assoc. for the Study of Pain*, Vol. XXI No. 5, Dec. 2013.

427. In materials Manufacturer Defendants produced, sponsored or controlled, Manufacturer Defendants instructed patients and prescribers that patients could remain on the same dose indefinitely, assuaging doctors' concerns about starting patients on opioids or increasing their doses during treatment, or about discontinuing their patients' treatment as doses escalated. These claims were not supported by scientific evidence.

428. PURDUE sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* taught that dose escalations are "sometimes necessary," even indefinite ones, but did not disclose the risks from high-dose opioids. This publication is still available online.

429. PURDUE sponsored a CME entitled *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME was edited by KOL, Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

430. PURDUE's *In the Face of Pain* website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will. In doing so, PURDUE exerted undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands.

431. PURDUE presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders" challenging the correlation between opioid dosage and overdose.

432. PURDUE's sales representatives assured New York State and City of Syracuse prescribers that opioids were just as effective for treating patients long term and omitted any discussion that increased tolerance would require increasing, and increasingly higher and dangerous

doses.

433. CEPHALON and PURDUE sponsored APF's *Treatment Options: A Guide for People Living with Pain* claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide taught that opioids differ from NSAIDs because they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The guide fails to disclose heightened risks at elevated doses. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose when the true figure was closer to 3,200 at the time.¹²⁸ This guide is still available for sale online.

434. CEPHALON sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

435. ENDO sponsored a website, *painknowledge.com*, which claimed in 2009 that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.

436. ENDO distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy, entitled, *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was published on ENDO's website. In Q&A format, it asked, "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. ... You won't 'run out' of pain relief."

437. JANSSEN sponsored a patient education guide entitled *Finding Relief Pain*

¹²⁸ Tarone, Robert E. et al., "Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies," *Am J Ther.* 2004 Jan-Feb;11(1):17-25.

Management for Older Adults (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

438. ACTAVIS' predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on ACTAVIS' acquisition of its predecessor's marketing materials along with the rights to Kadian, ACTAVIS continued to use these materials in 2009 and beyond.

439. Documents from a 2010 sales training indicate that ACTAVIS trained its sales force that "individualization" of opioid therapy depended on increasing doses "until patient reports adequate analgesia" and to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose."

440. ACTAVIS further counseled its sales representatives that the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician "comfort level" which could be overcome or used as a tool to induce them to switch to ACTAVIS' opioid Kadian.

441. PURDUE's, CEPHALON's, JANSSEN's, DEPOMED's, ENDO's, MALLINCKRODT's, ACTAVIS' and/or INSYS' sales representatives conveyed, and continue to convey to New York State, Onondaga County and/or City of Syracuse prescribers, the message that opioids were safe, even at higher doses. The Individual Defendants conveyed through their messages that opioids were safe, even at higher doses, which was false and not supported by scientific evidence.

442. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose

opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."

443. The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents *per* day. The 2016 CDC Guideline reinforces earlier findings announced by the FDA.

444. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."¹²⁹

G. Manufacturer Defendants Deceptively Omit or Minimize The Effects Of Opioids And Overstate Risks Of Alternative Forms Of Pain Treatment.

445. In materials they produced, sponsored or controlled, Manufacturer Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs. None of these claims was supported by scientific evidence.

446. The Manufacturer Defendants each made false statements and published deceptive materials that contained claims and/or omissions about the risks of opioids, including, in comparison with NSAIDs.

¹²⁹ 2016 CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016, <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>

447. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Manufacturer Defendants routinely ignored the risks of hyperalgesia, a “known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;”¹³⁰ hormonal dysfunction;¹³¹ decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;¹³² neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety. Post-traumatic stress disorder and anxiety also often accompany chronic pain symptoms.¹³³

448. PURDUE misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours - a fact that PURDUE has known at all times relevant to this action. According to PURDUE's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders PURDUE's promise of 12 hours of relief false and deceptive, it also makes

¹³⁰ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013).

¹³¹ See Daniell, H.W., “Hypogonadism in Men Consuming Sustained-Action Oral Opioids, *J Pain*. 2002 Oct; 3(5):377-84.

¹³² See Bernhard M., “The Risk of Fall Injury in Relation to Commonly Prescribed Medications Among Older People – a Swedish Case-Control Study,” *European Journal of Public Health*, Volume 25, Issue 3, 1 June 2015, Pages 527–532.

¹³³ Seal, Karen H., “Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan,” 307(9) *J. Am. Med. Ass’n* 940- 47 (2012).

OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

449. PURDUE sponsored a CME issued by the American Medical Association in 2003, 2007, 2010 and 2013, and the 2013 version is still available for CME credit. The CME, Overview and Management Options, was edited by KOL Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

450. PURDUE sales representatives told New York State and City of Syracuse prescribers that at NSAID's were more toxic than opiates.

451. Among Defendants' other unlawful, unfair and fraudulent misconduct, CEPHALON deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited CEPHALON from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse - which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

452. Despite this, CEPHALON conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for

which it was not approved, appropriate, or safe. As part of this campaign, CEPHALON used CMEs, speaker programs, paid consultant doctors, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example: a) CEPHALON paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online; b) CEPHALON's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and c) In December 2011, CEPHALON widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* - three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" - and not just cancer pain.

453. CEPHALON's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

454. CEPHALON sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opiates differ from NSAIDS in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of

NSAIDs increase if “taken for more than a period of months,” with no corresponding warning about opioids.

455. CEPHALON’s sales representatives told New York State and City of Syracuse prescribers that NSAIDS were more toxic than CEPHALON’s opioids.

456. Jansen sponsored a patient education guide titled Finding Relief: Pain Management for Older Adults (2009), which its personnel reviewed and approved and its sales force distributed. This publication described the advantages and disadvantages of NSAID's on one page, and the myths/facts of opioids on the facing page. The disadvantages of NSAIDs are described as “involving stomach upset or bleeding,” “kidney or liver damage of taking of high doses or for a long time,” “adverse reactions in people with asthma,” and “can increase the risk of heart attack and stroke.” The only adverse effects of opioids listed are “upset stomach or sleepiness”, which the brochure claims will go away, and constipation.

457. JANSSEN sales representatives told New York State and City of Syracuse prescribers that Nucynta was not an opioid, making it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is an opioid and has the same effects as other opioids.

458. APF’s *Exit Wounds*, sponsored by PURDUE and JANSSEN, with grants provided by ENDO, omits warnings of the risk of potentially fatal interactions between opioids and certain anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder, and, which would increase fatality risk. Exit Wounds also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.

459. ENDO distributed a “case study” to prescribers titled *Case Challenges in Pain*

Management: Opioid Therapy for Chronic Pain. The study cites an example, meant to be representative, of a patient “with a massive upper gastrointestinal bleed believe to be related to his protected use of NSAID's (over eight years), and recommends treating with opioids instead.

460. ENDO sponsored a website, painknowledge.com, through APF and an NIPC, which contains a flyer called *Pain: Opiate Therapy*. This publication included a list of adverse events from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. ENDO continued to provide funding for this website through 2012, and closely track unique visitors to it.

461. ENDO sales representative told New York State and City of Syracuse prescribers the NSAIDs were more toxic than opioids.

462. MALLINCKRODT's sales representatives told New York State and City of Syracuse prescribers that NSAIDS were more toxic than opioids.

463. Documents from a 2010 sales training indicate that ACTAVIS trained its sales force that the ability to escalate doses during long term opioid therapy, without hitting a dose ceiling, made opioid use safer than other forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDS.

464. ACTAVIS trained physician-speakers that “maintenance therapy with opioids can be safer than long term use of other analgesics”, including NSAIDS, in older persons.

465. ACTAVIS' Kadian sales representatives told New York State and City of Syracuse prescribers that NSAIDS were more toxic than opioids.

466. Defendants falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene

pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And, the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

467. Because of Manufacturer Defendants' campaign of deception, promoting opioids over safer and more effective drugs, often times through messaging spread by the Individual Defendants, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.¹³⁴

VIII. Manufacturer Defendants Engaged in Deceptive Marketing and Promoting, Both Branded and Unbranded Drugs, that Targeted and Reached New York State and City of Syracuse Prescribers

468. While Manufacturer Defendants worked in concert to expand the market for opioids, they also worked to maximize their individual shares of that market. Each Defendant promoted opioids for chronic pain through sales representatives (which Manufacturer Defendants called "detailers" to deemphasize their primary sales role) and small group speaker programs to contact individual prescribers nationwide and in City of Syracuse. By establishing close relationships with doctors, Manufacturer Defendants could disseminate their misrepresentations in targeted, one-

¹³⁴ Daubresse, M. et al., "Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States," 2000-2010, 51(10) Med. Care 870-78 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady. See also Mafi, JN et al., "Worsening Trends in the Management and Treatment of Back Pain," JAMA Intern Med. 2013 Sep 23;173 (17):1573-81.

on-one settings that allowed them to differentiate their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

469. Manufacturer Defendants' Detailers pitched opioids to general practitioners to treat common conditions such as back aches and knee pain. Sales Detailers showered prescribers with gifts, invited doctors to dinner seminars, and flew them to weekend junkets at resort hotels, where they were encouraged to prescribe opioids and promote it to colleagues back home.¹³⁵ PURDUE, for example, used presentations and training materials to train sales reps to remind doctors there is no ceiling on the amount of OxyContin a patient can be prescribed.¹³⁶

A. PURDUE

470. PURDUE promoted its branded opioids - principally, Oxycontin, Butrans, and Hysingla - and opioids generally in a campaign that consistently mischaracterized the risk of addiction and made deceptive claims about functional improvement. PURDUE did so through its sales force, branded advertisements, promotional materials, and speakers, as well as a host of materials produced by its third-party partners, most prominently APF. PURDUE's sales representatives and advertising also misleadingly implied that OxyContin provides a full 12 hours of pain relief, and its allied Front Groups and KOLs, including the Individual Defendants, conveyed the additional deceptive messages about opioids' safety at higher doses, the safety of alternative therapies, and the effectiveness of addiction screening tools.

471. Based on the highly coordinated and uniform nature of PURDUE's marketing, PURDUE conveyed these deceptive messages to New York and City of Syracuse prescribers. The materials that PURDUE generated in collaboration with third parties also were distributed or made

¹³⁵ Ryan, Harriet, et al., "'You want a Description of Hell?' Oxycontin's 12-Hour Problem," *The Los Angeles Times*, 5 May 2016. Web. 25 Oct. 2017.

¹³⁶ *Id.*

available in New York and City of Syracuse. PURDUE distributed these messages, or facilitated their distribution, in New York and City of Syracuse with the intent that New York and City of Syracuse prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

472. PURDUE and the other Manufacturer Defendants collected information about the highest prescribing doctors. For example, “PURDUE collected extensive evidence suggesting illegal trafficking of OxyContin and, in many cases, did not share it with law enforcement or cut off the flow of pills. A former PURDUE executive, who monitored pharmacies for criminal activity, acknowledged that even when the company had evidence pharmacies were colluding with drug dealers, it did not stop supplying distributors selling to those stores.”¹³⁷ Instead, sales detailers would continue to visit these places trafficking its opioids.

1. PURDUE’S Deceptive Direct Marketing

473. Like the other Defendants, PURDUE directly disseminated deceptive branded and unbranded marketing focused on minimizing the risks associated with the long-term use of opioids to treat chronic pain. PURDUE directed these messages to prescribers and consumers through its sales force and branded advertisements.

474. PURDUE engaged in in-person marketing to doctors in New York State and City of Syracuse and operated speakers’ bureau programs that included and targeted New York State and City of Syracuse prescribers. PURDUE had hundreds of sales representatives in 2007, many of which were devoted to promoting sales of OxyContin full time. Like the other Defendants’ detailers, PURDUE sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed, identically, across the country. These sales representatives were

¹³⁷ Girion, Lisa, “Dissecting an OxyContin Pipeline,” *Portland Press Herald*, 16 July 2016. Web. 25 Oct. 2017.

critical in delivering PURDUE's marketing strategies and talking points to individual prescribers.¹³⁸ Indeed, ENDO's internal documents indicate that pharmaceutical sales representatives employed by ENDO, ACTAVIS, and PURDUE discussed the AAPM/APS Guidelines, which as discussed above, deceptively concluded that the risk of addiction is manageable for patients regardless of past abuse histories, with doctors during individual sales visits.

475. PURDUE's spending on detailing reached its lowest point in 2006 and 2007, as the company faced civil and criminal charges for misbranding OxyContin. Since settling those charges in 2007, however, PURDUE sharply increased its quarterly spending on promotion through its sales force, from under \$5 million in 2007 to more than \$30 million by the end of 2014.

476. PURDUE also marketed its drugs through branded advertisements, which relied on, among other deceptive tactics, misleading statements about the efficacy and onset of OxyContin. As described above, PURDUE has marketed its drugs as effective for 12 hours. PURDUE knew, however, that these claims were misleading because, for many patients, the pain relief lasted for as little as eight hours, which led to end-of-dose failure and withdrawal symptoms and prompted doctors to prescribe or patients to take higher or more frequent doses of opioids, all of which increased the risk of abuse and addiction.

477. For example, a "Conversion and Titration Guide" submitted to the FDA and distributed to physicians by PURDUE, prominently referred to "Q12h OxyContin Tablets," meaning that each tablet is intended to "*offer your patient every-twelve-hour dosing.*" Other marketing materials directed at physicians and disseminated across the country in 2006 touted that OxyContin's "12-hour AcroContin Delivery System" is "*designed to deliver oxycodone over 12 hours,*" which offered patients

¹³⁸ But Purdue did not stop there. It also tracked around 1,800 doctors whose prescribing patterns demonstrated a probability that they were writing opioid prescriptions for addicts and drug dealers. Purdue kept the program secret for nine years and, when it finally did report information about these suspicious doctors to law enforcement authorities, it only did so with respect to 8% of them.

"life with Q12H relief." Those same marketing materials included a timeline graphic with little white paper pill cups only at "8AM" and, further down the line, at "8PM." They also proclaimed that OxyContin provides "*Consistent Plasma Levels Over 12 Hours*" and set forth charts demonstrating absorption measured on a logarithmic scale which fraudulently made it appear that levels of oxycodone in the bloodstream slowly tapered over a 12-hour time period.

478. PURDUE advertisements that ran in 2005 and 2006 issues of the *Journal of Pain* depict a sample prescription for OxyContin with "Q12h" handwritten. Another advertisement PURDUE ran in 2005 in the *Journal of Pain* touted OxyContin's "*Q12h dosing convenience*" and displayed two paper dosing cups, one labeled "8 am" and one labeled "8 pm," implying that OxyContin is effective for the 12-hour period between 8 a.m. and 8 p.m. Similar ads appeared in the March 2005 *Clinical Journal of Pain*.

479. Further, to this day, PURDUE includes prominent 12-hour dosing instructions in its branded advertising, such as in a 2012 "Conversion and Titration Guide", which states: "*Because each patient's treatment is personal/individualize the dose, Q12h OxyContin Tablets.*"

480. As outlined above, however, these statements are misleading because they fail to make clear that a 12-hour dose does not equate to 12 hours of pain relief. Nevertheless, PURDUE's direct marketing materials have misleadingly claimed that OxyContin offers 12-hour "*dosing convenience*."

481. As described below, PURDUE's deceptive statements regarding the efficacy of OxyContin were also carried into New York State and City of Syracuse by PURDUE's detailers.

482. PURDUE's direct marketing materials also misrepresented that opioids would help patients regain functionality and make it easier for them to conduct everyday tasks like walking, working, and exercising.

483. For example, in 2012, PURDUE disseminated a mailer to doctors titled “*Pain Vignettes*.” These “*vignettes*” consisted of case studies describing patients with pain conditions that persisted over a span of several months. One such patient, “Paul,” is described to be a “54-year old writer with osteoarthritis of the hands,” and the vignettes imply that an OxyContin prescription will help him work. None of these ads, however, disclosed the truth - that there is no evidence that opioids improve patients’ lives and ability to function (and there was substantial evidence to the contrary).

484. Some of the greatest weapons in PURDUE’s arsenal, however, were unbranded materials it directly funded and authored. These were in addition to the unbranded materials, described below, that PURDUE channeled through third parties.

485. In 2011, PURDUE published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse*, which deceptively portrayed the signs - and therefore the prevalence - of addiction. However, PURDUE knew, as described above, that OxyContin was used non-medically by injection less than 17% of the time. Yet, *Providing Relief, Preventing Abuse* prominently listed side effects of injection like skin popping and track marks as “Indications of Possible Drug Abuse” - downplaying much more prevalent signs of addiction associated with OxyContin use, such as asking for early refills, and making it seem that addiction only occurs when opioids are taken illicitly.

486. *Providing Relief, Preventing Abuse* also deceptively camouflaged the risk of addiction by falsely supporting the idea that drug-seeking behavior could, in fact, be a sign of “*pseudoaddiction*” rather than addiction itself. Specifically, it noted that the concept of “*pseudoaddiction*” had “emerged in the literature” to describe “[drug-seeking behaviors] in patients who have pain that has not been effectively treated.” Nowhere in *Providing Relief, Preventing Abuse*

did PURDUE disclose the lack of scientific evidence justifying the concept of “*pseudoaddiction*”, nor that it was coined by a PURDUE vice president.

487. *Providing Relief, Preventing Abuse* was available nationally and was intended to reach New York and City of Syracuse prescribers. As described below, the deceptive statements in *Providing Relief, Preventing Abuse* regarding addiction were the very same messages PURDUE directed at New York State and City of Syracuse prescribers through its sales force.

488. PURDUE also disseminated misrepresentations through two of its unbranded websites, *In the Face of Pain* and *Partners Against Pain*.

489. Consistent with PURDUE’s efforts to portray opioid treatment as “essential” for the proper treatment of chronic pain and label skepticism related to chronic opioid therapy as an “inadequate understanding” that leads to “inadequate pain control,” *In the Face of Pain* criticized policies that limited access to opioids as being “*at odds with best medical practices*” and encouraged patients to be “*persistent*” in finding doctors who will treat their pain. This was meant to imply that patients should keep looking until they find a doctor willing to prescribe opioids.

490. *In the Face of Pain* was available nationally and was intended to reach New York and City of Syracuse prescribers.

491. PURDUE also used its unbranded website *Partners Against Pain* to promote the same deceptive messages regarding risk of addiction that are described above and delivered by its sales representatives. On this website, PURDUE posted *Clinical Issues in Opioid Prescribing*, a pamphlet that was copyrighted in 2005. PURDUE distributed a hard-copy version of this pamphlet at least as of November 2006. *Clinical Issues in Opioid Prescribing* claimed that “illicit drug use and deception” were not indicia of addiction, but rather indications that a patient’s pain was undertreated.

The publication indicated that "[p]seudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated." In other words, PURDUE suggested that when faced with drug-seeking behavior from their patients, doctors should prescribe more opioids - turning evidence of addiction into an excuse to sell and prescribe even more drugs.

492. PURDUE's misleading messages and materials were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included New York State and City of Syracuse. As described above, PURDUE's nationwide messages would have reached New York State and City of Syracuse prescribers in a number of ways. For example, they were carried into New York State and City of Syracuse by PURDUE's sales representatives during detailing visits as well as made available to New York State and City of Syracuse patients and prescribers through websites and ads, including ads in prominent medical journals. They would have also been delivered to New York State and City of Syracuse prescribers by PURDUE's paid speakers, who were required by PURDUE policy and by FDA regulations to stay true to PURDUE's nationwide messaging.

493. PURDUE's sales representatives also misled prescribers about the efficacy of its abuse-deterrent opioid formulation ("ADF"). In 2010 PURDUE introduced "reformulated" OxyContin ("ADF OxyContin") that had a harder shell meant to make the pills more resistant to crushing. PURDUE's sales representatives deceptively marketed ADF OxyContin as a solution to opioid abuse. In 2014, PURDUE launched Hysingla ER, an opioid with purportedly similar abuse-deterrent properties.

494. But ADF OxyContin as no solution to opioid abuse. As noted by the FDA, "the tamper-resistant properties will have no effect on abuse by the oral route (the most common

mode of abuse).” Further, a 2015 study showed that *one-third* of patients were able to defeat the so-called abuse-deterrent properties to inhale or inject the drug.

495. PURDUE’s sales representatives use these abuse-deterrent properties to distinguish their drugs from competitors. Their specific tactics include: (i) claiming that PURDUE’s ADF opioids *prevent* tampering and could not be crushed or snorted; (ii) claiming that PURDUE’s ADF opioids *reduce* abuse and diversion; (iii) asserting for suggesting that PURDUE’s ADF opioids are “safer” than other opioids; and (iv) failing to disclose that PURDUE’s ADF opioids do not actually impact oral abuse or misuse.

496. Thus, even though PURDUE faced increased competition from other opioid drugs, it was able to maintain and even expand its sales by convincing health care professionals that ADF OxyContin was a safer option. As late as 2015, PURDUE’s sales representatives were telling physicians ADF OxyContin was “addiction resistant” and had “abuse-deterrent technology.”

2. PURDUE’s Deceptive Third-Party Statements

497. PURDUE’s efforts were not limited to making misrepresentations through its own sales force and its own branded and unbranded marketing materials. As described above, PURDUE knew that regulatory constraints restricted what it was able to say about its drugs through direct marketing. For this reason, like the other Defendants, PURDUE enlisted the help of third parties to release misleading information about opioids. The most prominent was APF.

a. APF

i. PURDUE’s Control of APF

498. PURDUE exercised considerable control over APF, which published and disseminated the most blatant falsehoods regarding chronic opioid therapy. Their relationship,

and several of the APF publications, is described in detail below.

499. PURDUE exercised its dominance over APF over many projects and years. PURDUE was APF's second-biggest donor, with donations totaling \$1.7 million. PURDUE informed APF that the grant money reflected PURDUE's effort to "strategically align its investments in nonprofit organizations that share [its] business interests," making clear that PURDUE's funding depended upon APF continuing to support PURDUE's business interests. Indeed, PURDUE personnel participated in a March 2011 call with APF's "Corporate Roundtable," where they suggested that APF "[s]end ambassadors to talk about pain within companies and hospitals." Thus, PURDUE suggested what role APF could play that would complement its own marketing efforts. On that call, PURDUE personnel also committed to provide APF with a list of "industry state advocates" who could help promote chronic opioid therapy, individuals and groups that, upon information and belief, APF reached out to. PURDUE personnel remained in constant contact with their counterparts at APF.

500. This alignment of interests was expressed most forcefully in the fact that PURDUE hired APF to provide consulting services on its marketing initiatives. PURDUE and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave PURDUE substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular PURDUE "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled PURDUE to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave PURDUE - but not APF - the right to end the project (and, thus, APF's funding) for any reason. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF's lack of

independence and willingness to harness itself to PURDUE's control and commercial interests, which would have carried across all of APF's work.

501. PURDUE used this Agreement to conduct work with APF on the *Partners Against Pain* website. *Partners Against Pain* is a PURDUE-branded site, and PURDUE holds the copyright. However, its ability to deploy APF on this project illustrates the degree of control PURDUE exercised over APF. In 2011, it hired an APF employee to consult on the *Partners Against Pain* rollout, to orchestrate the media campaign associated with the launch of certain content on the website, and to make public appearances promoting the website along with a celebrity spokesperson. PURDUE contemplated paying this consultant \$7,500 in fees and expenses for 26 hours of work. PURDUE would require this consultant “to discuss and rehearse the delivery of [PURDUE’s] campaign messages” and PURDUE committed that “[m]essage points will be provided to [the] Consultant in advance and discussed on [a planned] call.” At all times, decisions regarding the final content on the *Partners Against Pain* website were “at the sole discretion of Purdue.”

502. APF also volunteered to supply one of its staff (a medical doctor or a nurse practitioner) to assist PURDUE as a consultant and spokesperson in connection with the launch of one of PURDUE's opioid-related projects, *Understanding & Coping with Lower Back Pain*, which appeared on *Partners Against Pain*. One of the consultants was APF's paid employee, Mickie Brown. The consultant's services would be provided in return for \$10,000 in consulting fees for APF and \$1,500 in honoraria for the spokesperson. All documents used by the consultant in her media appearances would be reviewed and approved by individuals working for PURDUE. PURDUE initiated this project, and it was not until later that APF worried about "how PURDUE sees this program fitting in with our [existing] grant request.”

503. Given the financial and reputational incentives associated with assisting PURDUE in this project and the direct contractual relationship and editorial oversight, APF personnel were acting under PURDUE's control at all relevant times with respect to *Partners Against Pain*.

504. PURDUE often asked APF to provide "patient representatives" for *Partners against Pain*, and APF fulfilled these requests. Moreover, APF staff and board members and Front Groups ACPA and AAPM, among others (such as Dr. Lynn Webster), appear on *Inthefaceofpain.com*, as "Voices of Hope" - "champions passionate about making a difference in the lives of people who live with pain" and providing "inspiration and encouragement" to pain patients. APF also contracted with PURDUE for a project on back pain where, among other things, it provided a patient representative who agreed to attend a PURDUE-run "media training session."

505. According to an Assurance of Voluntary Compliance ("AVC") entered into between the New York Attorney General and PURDUE Pharma on August 19, 2015, *Inthefaceofpain.com* received 251,648 page views between March 2014 and March 2015. Except in one document linked to the website, *Inthefaceofpain.com* makes no mention of opioid abuse or addiction. PURDUE's copyright appears at the bottom of each page of the website, indicating its ownership and control of its content. There is no other indication that 11 of the individuals who provided testimonials on *Inthefaceofpain.com* received payments, according to the AVC, of \$231,000 for their participation in speakers' programs, advisory meetings and travel costs between 2008 and 2013. Therefore, the New York Attorney General found PURDUE's failure to disclose its financial connections with these individuals had the potential to mislead consumers by failing to disclose the potential bias of these individuals.

506. Nowhere was PURDUE's influence over APF so pronounced as it was with the APF's "*Pain Care Forum*" ("PCF"). It appears that PCF was and continues to be run not by APF, but by Defendant PURDUE's in-house lobbyist, Burt Rosen. As described by a former drug company employee, Burt Rosen was able to tell PCF "what to do and how to do it," and also asserted that this allowed him to run APF. According to this employee, to Rosen's thinking, "PCF was APF, which was PURDUE." The group meets regularly in-person and via teleconference and shares information through an email listserv.

507. In 2011, APF and another third-party advocacy group, the Center for Practical Bioethics, were contemplating working together on a project. Having reviewed a draft document provided by the Center for Practical Bioethics, the APF employee cautioned that "*this effort will be in cooperation with the efforts of the PCF*" and acknowledged that "*I know you have reservations about the PCF and pharma involvement, but I do believe working with them and keeping the lines of communications open is important.*" The Center for Practical Bioethics CEO responded by indicating some confusion about whom to speak with, asking "[i]s Burt Rosen the official leader" and reflecting what other sources have confirmed.

508. In 2007, the PCF Education Subgroup, consisting of drug companies PURDUE and Alkermes, and Front Groups APF and ACPA (self-described as "industry-funded" groups), developed a plan to address a perceived "lack of coordination" among the industry and pro-opioid professional and patient organizations. PCF members agreed to develop simplified "key messages" to use for public education purposes. Their messages were reflected in programs like NIPC's *Let's Talk Pain* (put together by ENDO and APF), and PURDUE's *In the Face of Pain*.

509. When the FDA required drug companies to fund CMEs related to opioid risks in connection with its 2009 REMS, PURDUE, along with these Front Groups, worked through the PCF

to ensure that, although it was mandatory for drug companies to fund these CMEs, it would not be mandatory for prescribers to attend them. A survey was circulated among Defendants ENDO, JANSSEN, and PURDUE, which predicted that the rates of doctors who would prescribe opioids for chronic pain would fall by 13% if more than four hours of mandatory patient education were required in connection with the REMS. With a push from PCF, acting under PURDUE's direction, they were not.

510. APF showed its indebtedness to PURDUE and its willingness to serve its corporate agenda by testifying on the company's behalf at a July 2007 hearing before the Senate Judiciary Committee "evaluating the propriety and adequacy of the OxyContin criminal settlement."¹³⁹ Despite its ostensible role as a patient advocacy organization, APF was willing to overlook substantial evidence - resulting in the jailing of PURDUE executives - that PURDUE blatantly, and despite its clear knowledge to the contrary, told physicians and patients that OxyContin was "rarely" addictive and less addictive than other opioids. Like PURDUE and despite the leadership of numerous medical doctors and researchers on its board, APF ignored the truth about opioids and parroted PURDUE's deceptive messaging. APF testified on PURDUE's behalf that addiction was a "rare problem" for chronic pain patients and asserted: *"[T]he scientific evidence suggests that addiction to opioids prescribed by legitimate chronic non-cancer pain patients without prior histories of substance abuse using the medication as directed is rare. Furthermore, no causal effect has been demonstrated between the marketing of OxyContin and*

¹³⁹ *Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Before the S. Comm. on the Judiciary 110th Cong. 46-50, 110-116 (2007) (statements of Dr. James Campbell, Chairman, APF). Purdue was also able to exert control over APF through its relationships with APF's leadership. Purdue-sponsored KOLs Dr.s Russell Portenoy and Scott Fishman chaired APF's board. Another APF board member, Dr. Perry Fine, also received consulting fees from Purdue. APF board member Lisa Weiss was an employee of a public relations firm that worked for both Purdue and APF. Weiss, in her dual capacity, helped vet the content of the Purdue-sponsored Policymaker's Guide, which is described below.*

the abuse and diversion of the drug." There was, and is, no scientific support for those statements.

511. APF President Will Rowe reached out to Defendants - including PURDUE - rather than his own staff to identify potential authors to draft an answer to an article critical of opioids that appeared in the *Archives of Internal Medicine* in 2011.

512. PURDUE's control over APF shaped and was demonstrated by specific APF, pro-opioid publications. These publications had no basis in science and were driven (and can only be explained) by the commercial interest of pharmaceutical companies—PURDUE chief among them.

ii. *A Policymaker's Guide*

513. PURDUE provided significant funding to and was involved with APF in creating and disseminating *A Policymaker's Guide to Understanding Pain & Its Management*, which was originally published in 2011 and is available online to this day. *A Policymaker's Guide to Understanding Pain & Its Management* misrepresented that that there were studies showing that the use of opioids for the long-term treatment of chronic pain could improve patients' ability to function.

514. Specifically, *A Policymaker's Guide to Understanding Pain & Its Management* claimed that "multiple clinical studies" demonstrated that "opioids... are very effective in improving [d]aily function, [p]sychological health [and] [o]verall health-related quality of life for people with chronic pain" and implied that these studies established that the use of opioids long-term led to functional improvement. The study cited in support of this claim specifically noted that there were no studies demonstrating the safety of opioid long-term and noted that "[f]or functional outcomes, the other [studied] analgesics were significantly more effective than were opioids."¹⁴⁰

515. The *Policymaker's Guide* also misrepresented the risk of addiction. It claimed that

¹⁴⁰ Andrea D. Furlan et. al. *Opioids for chronic noncancer pain: a meta analysis of effectiveness and side effects*. 174(11) *CAN. Med. Ass'n J.* 1589 (2006).

pain generally had been “undertreated” due to “[m]isconceptions about opioid addiction” and that “less than 1% of children treated with opioids become addicted.”

516. Moreover, the *Policymaker's Guide* attempted to distract doctors from their patients' drug-seeking behavior by labeling it as “*pseudoaddiction*”, which, according to the guide, “describes patient behaviors that may occur when pain is undertreated.” Like *Partners Against Pain*, *A Policymaker's Guide* noted that “[p]seudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated.” The similarity between these messages regarding pseudo-addiction highlights the common, concerted effort behind PURDUE's deceptive statements.

517. The *Policymaker's Guide* further misrepresented the safety of increasing doses of opioids and deceptively minimized the risk of withdrawal. For example, the *Policymaker's Guide* claimed that “[s]ymptoms of physical dependence” on opioids in long-term patients “can often be ameliorated by gradually decreasing the dose of medication during discontinuation” while omitting the significant hardship that often accompanies cessation of use. Similarly, the *Policymaker's Guide* taught that even indefinite dose escalations are “sometimes necessary” to reach adequate levels of pain relief, but it completely omitted the safety risks associated with increased doses.

518. PURDUE provided substantial assistance toward the creation and dissemination of the *Policymaker 's Guide*, which APF ultimately disseminated on behalf of Defendants, including PURDUE. PURDUE provided \$26,000 in grant money to fund the development and dissemination of its content. PURDUE kept abreast of the content of the guide as it was being developed, and, based on the periodic reports APF provided to PURDUE regarding its progress on the *Policymaker's Guide*, had editorial input into its contents.

519. The *Policymaker's Guide* was posted online and was available to and intended to reach New York State and City of Syracuse prescribers and consumers. As described below, the deceptive statements in *Policymaker's Guide* regarding addiction and functionality were the very same messages PURDUE directed at New York and City of Syracuse through its own sales force.

iii. *Treatment Options: A Guide for People Living with Pain*

520. PURDUE's partnership with APF did not end with the *Policymaker's Guide*. PURDUE also substantially assisted APF by sponsoring *Treatment Options: A Guide for People Living with Pain*, starting in 2007. Based on PURDUE's control of other APF projects, PURDUE also would have exercised control over *Treatment Options*.

521. *Treatment Options* is full of misrepresentations regarding the safety and efficacy of opioids. For example, *Treatment Options* misrepresented that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that, when used properly, opioids "give [pain patients] a quality of life [they] deserve."

522. Further, as outlined above, *Treatment Options* claimed that addiction is rare and, when it does occur, involves unauthorized dose escalations, patients who receive opioids from multiple doctors, or theft, which paints a narrow and misleading portrait of opioid addiction.

523. *Treatment Options* also promoted the use of opioids to treat long-term chronic pain by denigrating alternate treatments, most particularly NSAIDs. *Treatment Options* noted that NSAIDs can be dangerous at high doses and inflated the number of deaths associated with NSAID use, and distinguished opioids as having less risk. According to *Treatment Options*, NSAIDs were different from opioids because opioids had "no ceiling dose," which was beneficial since some patients "need" larger doses of painkillers than they are currently prescribed. *Treatment Options* warned that the risks associated with NSAID use increased if NSAIDs were "taken for more than a

period of months,” but deceptively omitted any similar warning about the risks associated with the long-term use of opioids.

524. *Treatment Options* was posted online and remains online today. It was available to and intended to reach New York State and City of Syracuse prescribers and patients. As described below, the deceptive statements in *Treatment Options* regarding addiction and functionality echo the messages PURDUE directed at New York State and City of Syracuse through its own sales force.

iv. Exit Wounds

525. PURDUE also engaged in other promotional projects with and through APF. One such project was the publication and distribution of *Exit Wounds*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain.

526. PURDUE provided APF with substantial assistance in distributing *Exit Wounds* to various Wounded Warriors and Veterans organizations throughout the nation by providing grant money and other resources.

527. Upon information and belief, APF mailed copies of *Exit Wounds* to Wounded Warriors and Veterans organizations in New York State and/or City of Syracuse.

b. PURDUE’s Work with Other Third-Party Front Groups and KOLs

528. PURDUE also provided other third-party Front Groups with substantial assistance in issuing misleading statements regarding the risks, benefits, and superiority of opioids for the long-term treatment of chronic pain.

i. FSMB—*Responsible Opioid Prescribing*

529. In 2007, PURDUE sponsored FSMB’s *Responsible Opioid Prescribing*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain.

530. PURDUE spent \$150,000 to help FSMB distribute *Responsible Opioid Prescribing*. The book was distributed nationally, and was available to and intended to reach prescribers in New York State and in the City of Syracuse.

ii. AGS- *Pharmacological Management of Pain in Older Persons*

531. Along with JANSSEN, PURDUE worked with the AGS on a CME to promote the 2009 guidelines for the *Pharmacological Management of Pain in Older Persons*. As discussed above, these guidelines falsely claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse" when the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that "[a]ll patients with moderate to severe pain should be considered for opioid therapy (low quality of evidence, strong recommendation)."

532. Controversy surrounding earlier versions of AGS guidelines had taught AGS that accepting money directly from drug companies to fund the guidelines' development could lead to allegations of bias and "the appearance of conflict." Accordingly, AGS endeavored to eliminate "the root cause of that flack" by turning down commercial support to produce the 2009 Guidelines. Having determined that its appearance of independence would be tarnished if it accepted drug company money to create the content, AGS decided to develop the guidelines itself and turn to the drug companies instead for funding to *distribute* the pro-drug company content once it had been created. As explained by AGS personnel, it was AGS's "strategy that we will take commercial support to disseminate [the 2009 Guidelines] if such support is forthcoming." AGS knew that it would be difficult to find such support unless the report was viewed favorably by opioid makers.

533. AGS sought and obtained grants from ENDO and PURDUE to distribute

Pharmacological Management of Persistent Pain in Older Persons. As a result, the publication was distributed nationally, and was available to and was intended to reach New York State and City of Syracuse prescribers. Indeed, internal documents of another Defendant, ENDO, indicate that pharmaceutical sales representatives employed by PURDUE discussed treatment guidelines that minimized the risk of addiction to opioids with doctors during individual sales visits.¹⁴¹

iii. *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*

534. PURDUE sponsored a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids. This CME was presented at various locations in the United States.

iv. *Managing Patient's Opioid Use: Balancing the Need and Risk*

535. PURDUE also sponsored a 2011 CME taught by KOL Dr. Lynn Webster via webinar titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation likewise deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose deaths.” At the time, Dr. Lynn Webster was receiving significant funding from PURDUE. Versions of Dr. Lynn Webster's Opioid Risk Tool appear on, or are linked to, websites run by PURDUE (and other Defendants). The webinar was available to and was intended to reach New York State and City of Syracuse prescribers.

¹⁴¹ As described above, Purdue also provided substantial support for the AAPM/APS guidelines. In 1997 AAPM and APS consensus statement *The Use of Opioids for the Treatment of Chronic Pain* was authored by one of its paid speakers, and 14 out of 21 panel members who drafted the AAPM/APS Guidelines received support from Defendants Janssen, CEPHALON, ENDO, and Purdue.

v. *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*

536. PURDUE also sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. *Path of the Patient* is devoted entirely to treating chronic pain with opioids. Although the program purports to instruct a treating physician how to manage chronic pain in younger adults at risk for abuse, it does no such thing. This "educational" program, addressing treatment of a population known to be particularly susceptible to opioid addiction, presents none of the alternative treatment options available, but only discusses treatment of chronic pain with opioids.

537. In a role-play in *Path of the Patient*, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone pills as directed. The doctor reports that the pharmacy called him because of the patient's early refills. The patient has a history of drug and alcohol abuse. Despite these facts, the narrator notes that, because of a condition known as "*pseudoaddiction*," the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor in the role play treats this patient by prescribing a high-dose, long acting opioid. This CME was available online and was intended to reach New York State and City of Syracuse prescribers.

vi. *Overview of Management Options*

538. PURDUE also sponsored a CME titled *Overview of Management Options* and issued by the American Medical Association in 2003, 2007, and 2013 (the latter of which is still available for CME credit). The CME was edited by KOL Dr. Russell Portenoy, among others. It deceptively instructed physicians that NSAIDs and other drugs, but not opioids, are unsafe at high doses. In fact, the data indicates that patients on high doses of opioids are more likely to

experience adverse outcomes than patients on lower doses of the drugs. Dr. Russell Portenoy received research support, consulting fees, and honoraria from PURDUE (among others), and was a paid PURDUE consultant. This CME was presented online in the United States and was available to New York and City of Syracuse prescribers.

c. Purdue's Misleading Science

539. PURDUE also misrepresented the risks associated with long-term opioids use by promoting scientific studies in a deceptive way. In 1998, PURDUE funded two articles by Dr. Lawrence Robbins that were disseminated to and available to New York State and City of Syracuse prescribers, which showed that between 8% and 13% of the patients he studied became addicted to opioids - a troubling statistic for PURDUE, whose market and marketing, depended upon the claim that opioids were rarely addictive.¹⁴² PURDUE has these articles placed in headache-specific journals, where they would be less likely to be encountered by pain specialists or general practitioners. The first of these articles has been cited a mere 16 times: the second does not even appear on Google Scholar.

540. Five years later, PURDUE also funded a study of OxyContin in diabetic neuropathy patients, which was published in 2003. Notwithstanding that PURDUE-funded studies, testing PURDUE's own drugs, had previously indicated that addiction rates were between 8% and 13%. PURDUE's 2003 article reached back to the 1980 Porter-Jick Letter to support its claim that OxyContin was not commonly addictive. This article was placed in a prominent pain journal and has been cited 487 times.¹⁴³ While this article was drafted over a

¹⁴² Dr. Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) *Headache Q.* 135 (1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a long-acting Opioid for Severe Chronic Daily Headache*, 19 *Headache Q.* 305 (1999).

¹⁴³ C. Peter N. Watson et. al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial 1 painful diabetic neuropathy*, 105 *Pain* 71 (2003).

decade ago, it continues to be relied upon to further the misrepresentations that opioids are not addictive.

3. PURDUE's Deceptive Statements to New York State and City of Syracuse Prescribers and Patients

541. PURDUE directed the dissemination of the misstatements described above to New York State and City of Syracuse patients and prescribers through the Front Groups, KOLs, and publications described above, as well as through its substantial sales force in New York State and City of Syracuse and through advertisements in prominent medical journals. The deceptive statements distributed through each of these channels reflect a common theme of misrepresenting the benefits of PURDUE's opioids, unfairly portraying the risks of addiction associated with their use, and deceptively implying that they would improve patients' ability to function.

542. The deceptive message that OxyContin provided 12 hours of pain relief not only was available to reach New York State and City of Syracuse prescribers through nationally circulated advertising but was also carried directly into the offices of New York State and City of Syracuse doctors by PURDUE's sales representatives.

543. Likewise, the deceptive messages minimizing addiction were not only directed at New York State and City of Syracuse patients and prescribers through the publications circulated above, but also were disseminated directly by PURDUE's sales force.

544. PURDUE also used its sales force to disseminate misleading statements about the ability of opioids to improve functionality.

545. The experiences of specific prescribers confirm both that PURDUE's national marketing campaign included the misrepresentations described above, and that the company disseminated these same misrepresentations to New York and City of Syracuse prescribers and

consumers. In particular, these prescriber accounts reflect that PURDUE detailers omitted or minimized the risk of opioid addiction; claimed that PURDUE's drugs would be less problematic for patients because they had extended release mechanisms, were tamper proof; and were "steady state"; claimed that OxyContin would provide 12 hours of pain relief; represented that screening tools could help manage the risk of addiction; minimized the symptoms of withdrawal; claimed or implied that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

546. PURDUE sales representatives promoted OxyContin as being effective for a full 12 hours at least between 2008 and 2012; and as improving patients' sleep (an unsubstantiated functional improvement). PURDUE sales representatives also told prescribers that the reformulation of OxyContin prevented illegal drug use and that the formulation was "less addicting," rather than being harder to adulterate. PURDUE sales representatives also claimed in 2011 that the sustained-release property of OxyContin reduced patient "buzz," which is neither based on scientific evidence nor true.

547. PURDUE sales representatives also promoted its Schedule III opioid Butrans as having low or little abuse potential. Other misrepresentations regarding Butrans include telling prescribers that Butrans had a "ceiling effect," reducing its abuse potential; and, that Butrans was "essentially tamperproof," even though there is nothing in the label to support such claims.

548. PURDUE, and the other Manufacturer Defendants, compensated sales Detailers for this conduct:

- A West Virginia supervisor for PURDUE told one of his highest performing sales detailers in a 1999 letter she could "blow the lid off" her sales and earn a trip to Hawaii if she persuaded more doctors to write larger doses.
- In an August 1996 memo headlined "\$\$\$\$\$\$\$\$\$\$\$\$\$\$\$ It's Bonus Time in

the Neighborhood!” a PURDUE manager reminded Tennessee detailers that raising dosage strength was the key to a big payday.¹⁴⁴

549. PURDUE, and the other Manufacturer Defendants, developed sophisticated methods for selecting doctors for sales visits based on the doctors’ prescribing habits. Under common industry practice, Manufacturer Defendants purchase and closely analyze prescription sales data from IMS Health, a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their sales practices. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above throughout the United States, including doctors in City of Syracuse.

550. The IMS Health data was vital to PURDUE’s, and the other Manufacturer Defendants’, sales departments. Sales detailers working on commission could identify doctors writing a small number of opioid prescriptions who might be persuaded to write more. PURDUE, and the other Manufacturer Defendants, also could identify physicians writing large numbers of prescriptions.

551. The highest prescribing doctors were added to PURDUE’s confidential roster of physicians suspected of recklessly prescribing. PURDUE calls that list Region Zero and has been adding names to it since 2002. A LA Times investigation discovered the existence of that list. As of 2013, PURDUE acknowledged there were over 1,800 doctors in Region Zero. PURDUE had reported less than 8% on the list to authorities.¹⁴⁵

552. Like the other Defendants, PURDUE also promoted its opioids through a network of recruited, paid speakers, who have stated that they were required to stick to the company-approved messaging during speaking engagements.

¹⁴⁴ *Id.*

¹⁴⁵ Girion, Lisa, “Dissecting an OxyContin Pipeline,” *Portland Press Herald*, 16 July 2016. Web. 25 Oct. 2017.

553. PURDUE also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. PURDUE's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as PURDUE is legally obligated to do) or cease marketing to them, PURDUE used the list to demonstrate the high rate of diversion of OxyContin - the same OxyContin that PURDUE had promoted as less addictive - in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, PURDUE's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, PURDUE failed to take action - even where PURDUE employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, PURDUE did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that PURDUE's district manager described internally as "an organized drug ring." In doing so, PURDUE protected its own profits at the expense of public health and safety.

554. The State of New York's settlement with PURDUE specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, PURDUE continues to profit from the prescriptions of such prolific prescribers.

B. CEPHALON

555. At the heart of CEPHALON's deceptive promotional efforts was a concerted and sustained effort to expand the market for its branded opioids, Actiq and Fentora, far beyond their FDA-approved use in opioid-tolerant cancer patients. Trading on their rapid-onset formulation,

CEPHALON touted its opioids as the answer to "breakthrough pain" - a term its own KOL allies planted in the medical literature - whether cancer pain or not. CEPHALON promoted this message through its sales force, paid physician speakers, advertisements, and CMEs, even after the FDA issued the company warnings and rejected an expanded drug indication.

556. Even as it promoted Actiq and Fentora off-label, CEPHALON engaged in deceptive messages. It did so both directly - through detailing visits and speaker programs - and through the publications and CMEs of its third-party partners. These messages included misleading claims about functional improvement, addiction risk, "*pseudoaddiction*", and the safety of alternatives to opioids.

557. Based on the highly coordinated and uniform nature of CEPHALON's marketing, and as confirmed by both verbatim message data and prescriber interviews, CEPHALON conveyed these deceptive messages to New York State and City of Syracuse prescribers. The materials that CEPHALON generated in collaboration with third-parties also were distributed or made available in New York State and City of Syracuse. CEPHALON distributed these messages, or facilitated their distribution, in New York State and in the City of Syracuse with the intent that New York State and City of Syracuse prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

1. CEPHALON's Deceptive Direct Marketing

558. Like the other Manufacturer Defendants, CEPHALON directly engaged in misleading and deceptive marketing of its opioids through its sales force and branded advertisements. These messages were centrally formulated and intended to reach prescribers nationwide, including those practicing in the New York State and City of Syracuse area. CEPHALON also spent the money necessary to aggressively promote its opioid drugs, setting aside \$20 million to market Fentora in

2009 alone.

a. CEPHALON's Fraudulent Off-Label Marketing of Actiq and Fentora

559. Chief among CEPHALON's direct marketing efforts was its campaign to deceptively promote its opioids for off-label uses. CEPHALON reaps significant revenue from selling its opioids for treatment of chronic non-cancer pain. However, neither of its two opioid drugs Actiq or Fentora is approved for this purpose. Instead, both have indications that are very clearly and narrowly defined to limit their use to a particular form of cancer pain. Despite this restriction and in order to claim its piece of the broader chronic non-cancer pain market, CEPHALON deceptively and unlawfully marketed Actiq and later Fentora for patients and uses for which they were not safe, effective, or allowed, causing prescriptions to be written and paid and, grievously, patients to be injured and die. CEPHALON's efforts to expand the market for its drugs beyond cancer pain extended to New York State and City of Syracuse prescribers, many of whom were not oncologists.

i. CEPHALON launched its fraudulent marketing scheme for Actiq

560. CEPHALON's Actiq is a powerful opioid narcotic that is delivered to the bloodstream by a lollipop lozenge that dissolves slowly in the mouth. As described by one patient, Actiq "tastes like the most delicious candy you ever ate."¹⁴⁶

561. Actiq is appropriately used only to treat "breakthrough" cancer pain that cannot be controlled by other medications. Breakthrough pain is a short-term flare of moderate-to severe pain in patients with otherwise stable persistent pain. Actiq is a rapid-onset drug that takes effect within 10-15 minutes but lasts only a short time. It is also an extremely strong drug, considered to be at least 80 times more powerful than morphine. Fentanyl, a key ingredient in Actiq, has been linked to fatal respiratory complications in patients. Actiq is not safe in any dose for patients who are not opioid

¹⁴⁶ See John Carreyrou, *Narcotic 'Lollipop' is Big Seller Despite FDA Curbs*, *Wall St. J.*, Nov. 3, 2006.

tolerant, that is, patients who have taken specific doses of opioids for a week or longer and whose systems have acclimated to the drugs.

562. In 1998, the FDA approved Actiq "ONLY for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."¹⁴⁷ (emphasis in FDA document). Because of Actiq's dangers, wider, off-label uses - as the FDA label makes clear - are not permitted: "This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, ACTIQ is contraindicated in the management of acute or postoperative pain."¹⁴⁸

563. Actiq and Fentora are thus intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Unlike other drugs, as to which off-label uses are permitted but cannot be promoted by the drug maker, Actiq and Fentora are so potent that off label use for opioid naive patients is barred by the FDA, as their labels make clear.

564. Notwithstanding the drug's extreme potency and related dangers and the FDA's explicit limitations, CEPHALON actively promoted Actiq for chronic non-cancer pain - an unapproved, off-label use. CEPHALON marketed Actiq as appropriate for the treatment of various conditions including back pain, headaches, pain associated with sports-related injuries, and other conditions not associated with cancer for which it was not approved, appropriate, or safe.

565. Actiq's initial sales counted in the tens of millions of dollars, corresponding to its

¹⁴⁷ FDA Approval Letter for NDA 20-747 (Nov. 4, 1998) at 5. http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf.

¹⁴⁸ Actiq Drug Label. July 2011*l*. The 1998 version does not substantively differ: "Because life threatening hypoventilation could occur at any dose in patients not taking chronic opiates. Actiq is contra indicated in the management of acute or postoperative pain. This product must not be used in opioid non-tolerant patients." (Emphasis in original).

limited patient population. But by 2005, Actiq sales reached \$412 million, making it CEPHALON's second-highest selling drug. As a result of CEPHALON's deceptive, unlawful marketing, sales exceeded \$500 million by 2006.

**ii. CEPHALON fraudulently marketed Actiq's successor drug, Fentora –
October 1, 2006**

566. Actiq was set to lose its patent protection in September 2006. To replace the revenue stream that would be lost once generic competitors came to market, CEPHALON purchased a new opioid drug, Fentora, from Cima Labs and, in August 2005, submitted a New Drug Application ("NDA") to the FDA for approval. Like Actiq, Fentora is an extremely powerful and rapid-onset opioid. It is administered by placing a tablet in the mouth until it disintegrates and is absorbed by the mucous membrane that lines the inside of the mouth.

567. On September 25, 2006, the FDA approved Fentora, like Actiq, only for the treatment of breakthrough cancer pain in cancer patients who were already tolerant to around the-clock opioid therapy for their underlying persistent cancer pain. Fentora's unusually strong and detailed black box warning label - the most serious medication warning required by the FDA - makes clear that, among other things: "Fatal respiratory depression has occurred in patients treated with FENTORA, including following use in opioid non-tolerant patients and improper dosing. The substitution of FENTORA for any other fentanyl product may result in fatal overdose. Due to the risk of respiratory depression, FENTORA is contraindicated in the management of acute or postoperative pain including headache/migraine and in opioid non-tolerant patients."¹⁴⁹

568. When CEPHALON launched Fentora on October 1, 2006, it picked up the playbook it developed for Actiq and simply substituted in Fentora. CEPHALON immediately shifted

¹⁴⁹ Fentora Drug Label. February 2013, http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/02/1947s008lbl.pdf

100 general pain sales representatives from selling Actiq to selling Fentora to the very same physicians for uses that would necessarily and predictably be off-label. CEPHALON's marketing of Actiq therefore "primed the market" for Fentora. CEPHALON had trained numerous KOLs to lead promotional programs for Fentora, typically including off-label uses for the drug. CEPHALON billed Fentora as a major advance that offered a significant upgrade in the treatment of breakthrough pain generally - not breakthrough cancer pain in particular - from Actiq.

569. CEPHALON also developed a plan in 2007 to target elderly chronic pain patients, via a multi-city tour with stops at AARP events, YMCAs, and senior living facilities.

570. On February 12, 2007, only four months after the launch, CEPHALON CEO, Frank Baldino, told investors: "[W]e've been extremely pleased to retain a substantial portion, roughly 75% of the rapid onset opioid market. We executed our transition strategy and the results in our pain franchise have been better than we expected. With the successful launch of FENTORA and the progress in label expansion program, we are well positioned to grow our pain franchise for many years to come."¹⁵⁰

571. On May 1, 2007, just seven months after Fentora's launch, CEPHALON's then Executive Vice President for Worldwide Operations, Bob Roche, bragged to financial analysts that Fentora's reach would exceed even Actiq's. He described the company's successful and "aggressive" launch of Fentora that was persuading physicians to prescribe Fentora for ever broader uses. He identified two "major opportunities" - treating breakthrough cancer pain and: "The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain...."; and "We believe that a huge opportunity still

¹⁵⁰ See CEPHALON Q./ 2006 Earnings Call Transcript, Seeking Alpha (February 12, 2007, 8:48 PM EST) at 5, <http://seekingalpha.com/article/26813-CEPHALON-q4-2006-earnings-call-transcript>.

exists as physicians and patients recognize FENTORA as their first choice rapid onset opioid medication....[opioids are] widely used in the treatment of ... non-cancer patients"; and "Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%"; and "We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and wellbeing and the exciting growth potential that it has for CEPHALON"; and, finally, "In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous."¹⁵¹

iii. Reports of death and serious side effects led the FDA to issue a public health warning for Fentora - September 2007

572. On September 10, 2007, CEPHALON sent letters to doctors warning of deaths and other "serious adverse events" connected with the use of Fentora and indicating that "[t]hese deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients), improper dosing, and/or improper product substitution."¹⁵² The warning did not mention CEPHALON's deliberate role in the "improper patient selection."

573. Two weeks later, the FDA issued its own Public Health Advisory. The FDA

¹⁵¹ See CEPHALON Q1 2007 Earnings Call Transcript, Seeking Alpha (May 1, 2007, 8:48 PM EST) at 23, <http://seekingalpha.com/article/34163-CEPHALON-q1-2007-earnings-call-transcript?page=1>.

¹⁵² Letter from Jeffrey M. Dayna, M.D., Vice President, Medical Services, CEPHALON, Inc. to Healthcare Providers (Sept. 10, 2007), <http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM154439.pdf>.

emphasized, once again, that Fentora should be prescribed only for approved conditions and that dose guidelines should be carefully followed. The FDA Advisory made clear that several Fentora - related deaths had occurred in patients who were prescribed the drug for off-label uses. The FDA Advisory warned that Fentora should not be used for any off-label conditions, including migraines, post-operative pain, or pain due to injury, and that it should be given only to patients who have developed opioid tolerance. The Advisory reiterated that because Fentora contains a much greater amount of fentanyl than other opiate painkillers, it is not a suitable substitute for other pain killers.¹⁵³

574. CEPHALON's off-label marketing continued notwithstanding the regulatory scrutiny. CEPHALON's 2008 internal audit of its Sales & Marketing Compliance Programs concluded that marketing and tactical documents, as written, may be construed to promote off-label uses. The same report acknowledged that CEPHALON lacked a process to confirm that speakers' program participants were following CEPHALON's written, formal policies prohibiting off-label promotion, and that "non-compliant [CEPHALON Speaker Programs] may be taking place." Moreover, the report acknowledged that CEPHALON's "call universe" may include "inappropriate prescribers" - prescribers who had nothing to do with cancer pain.

iv. The FDA rejected CEPHALON's request for expanded approval of Fentora - May 6, 2008

575. CEPHALON filed a supplemental new drug application, ("sNDA"), asking the FDA to approve Fentora for the treatment of non-cancer breakthrough pain. CEPHALON admitted that Fentora already had been heavily prescribed for non-cancer pain, but argued that such

6

¹⁵³ FDA Public Health Advisory. *Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007). <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSatetyInformationforPatientsandProviders/ucm051273.htm>.

widespread use demonstrated why Fentora should be approved for these wider uses.¹⁵⁴

576. CEPHALON's application also conceded that "[t]o date, no medication has been systematically evaluated in clinical studies or approved by the FDA for the management of [breakthrough pain] in patients with chronic persistent non-cancer-related pain."¹⁵⁵

577. In response to CEPHALON's application, the FDA presented data showing that 95% of all Fentora use was for treatment of non-cancer pain.¹⁵⁶ By a vote of 17-3, the relevant Advisory Committee - a panel of outside experts - voted against recommending approval of CEPHALON's sNDA for Fentora, citing the potential harm from broader use. On September 15, 2008, the FDA denied CEPHALON's application and requested, in light of Fentora's already off label use, that CEPHALON implement and demonstrate the effectiveness of proposed enhancements to Fentora's Risk Management Program. In December 2008, the FDA followed up with a formal request directing CEPHALON to submit a Risk Evaluation and Mitigation Strategy for Fentora.

v. The FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") warned CEPHALON about its misleading advertising of Fentora – March 26, 2009

578. Undeterred by the rejection of its sNDA, CEPHALON continued to use its general pain sales force to promote Fentora, off-label, to pain specialists as an upgrade over Actiq for the treatment of non-cancer breakthrough pain. Deceptively and especially dangerously, CEPHALON also continued to promote Fentora for use by all cancer patients suffering breakthrough cancer pain, and not simply those who were opioid tolerant.

¹⁵⁴ See *Fentora CII: Advisory Committee Briefing Document*, U.S. FDA Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008), <http://www.fcla.gov/ohrms/dockets/ac/08/briefing/2008-4356b2-02-CEPHALON.pdf>.

¹⁵⁵ *Id.*

¹⁵⁶ See Yoo Jung Chang & Lauren Lee, *Review of Fentora and Actiq Adverse Events from the Adverse Event Reporting System ("AERS") Database*, U.S. FDA Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008), <http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-02-FDAcorepresentations.ppt#289.1> (last visited Aug. 17, 2010).

579. On March 26, 2009, DDMAC issued a Warning Letter to CEPHALON, telling CEPHALON that its promotional materials for Fentora amounted to deceptive, off-label promotion of the drug.¹⁵⁷ Specifically, the Warning Letter asserted that a sponsored link on Google and other search engines for Fentora, which said "*[l]earn about treating breakthrough pain in patients with cancer,*"¹⁵⁸ was improper because it "misleadingly broaden[ed] the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora therapy ... when this is not the case."

580. DDMAC emphasized that Fentora's label was limited to cancer patients with breakthrough pain "**who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.**" (Emphasis in original). DDMAC explained that the advertisement was "especially concerning given that Fentora **must not** be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids." (Emphasis in original). DDMAC also warned CEPHALON that, based on a review of CEPHALON - sponsored links for Fentora on internet search engines, the company's advertisements were "misleading because they make representations and/or suggestions about the efficacy of Fentora, but fail to communicate **any** risk information associated with the use" of the drug. (Emphasis in original).

vi. CEPHALON continues to knowingly, deceptively, and illegally promote Fentora for off-label uses

581. CEPHALON's own market research studies confirm that its Fentora promotions

¹⁵⁷ Letter from Michael Sauers, Regulatory Review Officer, Division of Drug Marketing, Advertising and Communications to Carole S. Marchione, Senior Director and Group Leader, Regulatory Affairs (March 26, 2009), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticesofViolationLetterstoPharmaceuticalCompanies/UCM166238.pdf>.

¹⁵⁸ Screen shots of the sponsored link are available here:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticesofViolationLetterstoPharmaceuticalCompanies/UCM166240.pdf>

were not focused on the physicians who treat breakthrough cancer pain. CEPHALON commissioned several market research studies to determine whether oncologists provided an “adequate” market potential for Fentora. These studies' central goal was to determine whether oncologists treat breakthrough cancer pain themselves, or whether they refer such patients to general pain specialists. The first study, completed in 2007, reported that 90% of oncologists diagnose and treat breakthrough cancer pain themselves, and do not refer their breakthrough cancer pain patients to pain specialists. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88% of oncologists diagnose and treat breakthrough cancer pain themselves and rarely, if ever, refer those patients to general pain specialists. (One reason that general pain specialists typically do not treat oncological pain is that the presence of pain can, in itself, be an indicator of a change in the patient's underlying condition that should be monitored by the treating oncologist.)

582. CEPHALON was aware that physicians were prescribing Fentora for off-label uses.

583. CEPHALON was also aware that its detailing had an impact on prescription rates.

584. In 2011, CEPHALON wrote and copyrighted an article titled “*2011 Special Report: An Integrated Risk Evaluation and Risk Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*” that was published in *Pain Medicine News*. The article promoted CEPHALON’s drugs for off-label uses by stating that the “judicious use of opioids can facilitate effective and safe management of chronic pain” and noted that Fentora “has been shown to be effective in treatment of [break through pain] associated with multiple causes of pain,” not just cancer.

b. CEPHALON’s Misrepresentation of the Risks Associated with the Use of Opioids for the Long-Term Treatment of Chronic Pain

585. CEPHALON’s conduct in marketing Actiq and Fentora for chronic non-cancer

pain, despite their clear (and deadly) risks and unproved benefits, was an extension, and reaped the benefits of CEPHALON's generally deceptive promotion of opioids for chronic pain.

586. Along with deploying its sales representatives, CEPHALON also used speakers' bureaus to help reach prescribers. CEPHALON viewed each treating physician as a vehicle to generate prescriptions – whether written by that physician directly or caused indirectly by his or her influence over other physicians.

587. Having determined that speakers were an effective way to reach prescribers, CEPHALON set to work ensuring that its speakers would disseminate its misleading messages.

588. As with other Defendants, CEPHALON deployed the made-up concept of “*pseudoaddiction*” to encourage prescribers to address addictive behavior in the worst way possible - with more opioids.

589. Working with FSMB, CEPHALON also trained its speakers to turn doctors' fear of discipline on its head - doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with pain. Through this messaging, CEPHALON aimed to normalize the prescribing of opioids for chronic pain and failed to acknowledge the serious risks of long-term opioid use and its inappropriateness as a front-line treatment for pain.

590. Finally, CEPHALON also developed a guidebook called *Opioid Medications and REMS: A Patient's Guide*, which deceptively minimized the risks of addiction from the long-term use of opioids. Specifically, the guidebook claimed that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids,” which, as described above, is dangerously false. CEPHALON distributed the guidebook broadly, and it was available to and intended to reach prescribers in New York State and the City of Syracuse.

591. The misleading messages and materials CEPHALON provided to its sales force and its speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, without complete and accurate information about the risks, benefits, and alternatives. This deception was national in scope and included New York State and the City of Syracuse. As described above, CEPHALON's nationwide messages would have reached New York State and The City of Syracuse prescribers in a number of ways. For example, they were delivered in New York State and The City of Syracuse by CEPHALON's sales representatives in detailing visits and made available to New York State and The City of Syracuse patients and prescribers through websites and ads, including ads in prominent medical journals. They have also been delivered to New York State and The City of Syracuse prescribers by CEPHALON's paid speakers, who were required by CEPHALON policy to stay true to the company's nationwide messaging.

2. CEPHALON's Deceptive Third-Party Statements

592. Like all other Manufacturer Defendants, CEPHALON also relied on third parties to disseminate its messages through deceptive publications and presentations. By funding, developing and reviewing the content of, and distributing and facilitating the distribution of these messages, CEPHALON exercised editorial control over them. CEPHALON, in some instances, used its sales force to directly distribute certain publications by these Front Groups and KOLs, rendering those publications "labeling" within the meaning of §21 C.F.R. §1.3(a) and making CEPHALON responsible for their contents. CEPHALON also deployed its KOLs as speakers for talks and CMEs to selected groups of prescribers.

593. CEPHALON's relationship with several such Front Groups and KOLs - and the misleading and deceptive publications and presentations those relationships generated - are described below.

a. FSMB - Responsible Opioid Prescribing

594. In 2007, for example, CEPHALON sponsored and distributed through its sales representatives FSMB's *Responsible Opioid Prescribing*, which was drafted by a writer frequently hired by a consulting firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science and that distorted the risks and benefits of chronic opioid therapy in order to meet the demands of drug company sponsors.

595. *Responsible Opioid Prescribing* contained a number of deceptive statements. This publication claimed that because pain had a negative impact on a patient's ability to function, relieving pain, alone, would "reverse the effect and improve function." However, as described above, the truth was far more complicated as functional improvements made from increased pain relief were offset by a number of problems, including addiction.

596. *Responsible Opioid Prescribing* also misrepresented the likelihood of addiction by mischaracterizing drug-seeking behavior as "*pseudoaddiction*". It explained that "requesting drugs by name," engaging in "demanding manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding were all signs of "*pseudoaddiction*" and are likely the effects of undertreated pain, rather than true addiction. As described above, there is no scientific evidence to support the concept of "*pseudoaddiction*", and any suggestion that addictive behavior masquerades as "*pseudoaddiction*" is false.

597. CEPHALON spent \$150,000 to purchase copies of *Responsible Opioid Prescribing* in bulk. It then used its sales force to distribute these copies to 10,000 prescribers and 5,000 pharmacists nationwide. These were available to and intended to reach prescribers and pharmacists in New York State and the City of Syracuse.

b. APF - *Treatment Options: A Guide for People Living with Pain*

598. CEPHALON also exercised considerable control over the Front Group APF, which published and disseminated many of the most egregious falsehoods regarding chronic opioid therapy. Their relationship, and several of the APF publications, are described in detail below.

599. Documents indicate that CEPHALON provided APF with substantial assistance in publishing deceptive information regarding the risks associated with the use of opioids for chronic pain. An April 3, 2008, Fentora Assessment Strategy Tactics Team Meeting presentation outlines CEPHALON's strategy to prepare for a meeting at which the FDA Advisory Committee would consider expanding the indication of Fentora to include chronic, non-cancer pain. CEPHALON prepared by "reaching out to third-party organizations, KOLs, and patients to provide context, and where appropriate, encourage related activity." First among the Front Groups listed was APF.

600. CEPHALON was among the drug companies that worked with APF to persuade the Institute of Medicine of the National Academies (IOM) on issues related to chronic opioid therapy. APF President Will Rowe circulated a document to CEPHALON and other drug company personnel that contained key message points and suggested that they "[c]onsider using this document in your communications with members of the IOM Committee." According to Rowe, recipients should "consider this a working document which you can add to or subtract from." Rowe also advised that, if recipients "have an ally on that Committee," they should "consider sharing this document with that person."

601. CEPHALON personnel responded enthusiastically, with CEPHALON's Associate Director for Alliance Development stating her belief that "the document does a good

job of bringing together many important ideas.” CEPHALON reviewed and directed changes to this document, with the CEPHALON Associate Director thanking Rowe “for incorporating the points we had raised.” The close collaboration between CEPHALON and APF on this project demonstrates their agreement to work together to promote the use of opioids as an appropriate treatment for chronic pain.

602. CEPHALON’s influence over APF’s activities was so pervasive that APF’s President, Will Rowe, even reached out to Defendants - including CEPHALON - rather than his own staff to identify potential authors to draft an answer to an article critical of opioids that appeared in the *Archives of Internal Medicine* in 2011.

603. CEPHALON also sponsored APF’s *Treatment Options: A Guide for People Living with Pain*, starting in 2007. It is rife with misrepresentation regarding the risks, benefits, and superiority of opioids.

604. For example, *Treatment Options* deceptively asserts that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that when used properly, opioids “give [pain patients] a quality of life [they] deserve.” As described above, there is no scientific evidence corroborating that statement, and such statements are, in fact, false because available data demonstrate that patients on chronic opioid therapy are *less* likely to participate in life activities like work.

605. *Treatment Options* also claims that addiction is rare and is evident from patients’ conduct in self-escalating their doses, seeking opioids from multiple doctors, or stealing the drugs. *Treatment Options* further minimizes the risk of addiction by claiming that it can be avoided through the use of screening tools, like “opioid agreements,” which can “ensure [that patients] take the opioid as prescribed.” Nowhere does *Treatment Options* explain to

patients and prescribers that neither “opioid agreements” nor any other screening tools have been scientifically validated to decrease the risks of addiction, and the publication’s assurances to the contrary are false and deceptive as described above.

606. *Treatment Options* also promotes the use of opioids to treat chronic pain by painting a misleading picture of the risks of alternate treatments, most particularly NSAIDs. *Treatment Options* notes that NSAIDs can be dangerous at high doses, and attributes 10,000 to 20,000 deaths a year annually to NSAIDs overdose. According to *Treatment Options*, NSAIDs are different from opioids because opioids have “no ceiling dose,” which is beneficial since some patients “need” larger doses of painkillers than they are currently prescribed. These claims misleadingly suggest that opioids are safe even at high doses and omit important information regarding the risks of high-dose opioids, as discussed above.

607. Additionally, *Treatment Options* warns that the risks associated with NSAID use increase if NSAIDs are “taken for more than a period of months,” but deceptively omits any similar warning about the risks associated with the long-term use of opioids. As discussed above, this presentation paints a misleading picture of the risks and benefits of opioids compared with alternate treatments.

608. APF distributed 17,200 copies of *Treatment Options* in 2007 alone. It is currently available online and was intended to reach New York and The City of Syracuse prescribers and pharmacists.

c. Key Opinion Leaders and Misleading Science

609. CEPHALON also knew that its misleading messages would be more likely to be believed by prescribers if they were corroborated seemingly neutral scientific support.

610. CEPHALON caused the term “breakthrough pain” - a term it seeded in the

medical literature - to be used in articles published by practitioners and clinicians it supported. With funding from CEPHALON, for example, Dr. Russell Portenoy wrote an article that purported to expand the definition of breakthrough cancer pain to non-cancer indications, vastly expanding the marketing potential of CEPHALON's Fentora. The article was published in the nationally circulated *Journal of Pain* in 2006 and helped drive a surge in Fentora prescriptions.

611. The concept of "breakthrough pain" ultimately formed the sole basis for the central theme of promotional messages CEPHALON cited to support the approval and marketing of Actiq and Fentora, rapid-acting opioids which began to work very quickly but last only briefly. Neither of these drugs had a natural place in the treatment of chronic pain before CEPHALON's marketing campaign changed medical practice. A recent literature survey of articles describing non-cancer breakthrough pain calls into question the validity of the concept, suggesting it was not a distinct pain condition but a hypothesis to justify greater dosing of opioids. In other words, CEPHALON conjured the science of breakthrough pain in order to sell its drugs.

612. As one scholar has pointed out, references to breakthrough pain in articles published on the MEDLINE bibliographic database spiked in 1998 and again in 2006.¹⁵⁹ These spikes coincided with FDA's approval of Actiq and Fentora.

613. CEPHALON's paid doctors received some combination of research support, consulting fees, and honoraria from CEPHALON, and Dr. Portenoy was a paid consultant for the company. All told, CEPHALON has paid doctors more than 4.5 million for programs relating to its opioids since 2000.

d. Misleading Continuing Medical Education

¹⁵⁹ Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME, PharmedOut, Georgetown U. Med. Ctr.* (June 25, 2010), available at pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf.

614. CEPHALON developed sophisticated plans for the deployment of its KOLs, broken down by sub-type and specialty, to reach targeted groups of prescribers through CMEs.

615. CEPHALON used the CME programs it sponsored to deceptively portray the risks related to the use of opioids to treat chronic non-cancer pain and promote the off-label use of Actiq and Fentora.

616. In 2007 and 2008, CEPHALON sponsored three CMEs that each positioned Actiq and Fentora, and only Actiq and Fentora, as “rapid onset opioids” that would provide effective analgesia within the time period during which “breakthrough pain” was at its peak intensity. Although the CMEs used only the generic names of the drugs, the description of the active ingredient and means of administration means that a physician attending the CME knew it referred only to Actiq or Fentora.

617. The CMEs each taught attendees that there was no sound basis for the distinction between cancer and non-cancer “breakthrough pain,” and one instructed patients that Actiq and Fentora were commonly used in non-cancer patients, thus effectively Endorsing this use. *Optimizing Opioid Treatment for Breakthrough Pain*, offered online by Medscape, LLC from September 28, 2007, through December 15, 2008, was prepared by KOL Dr. Lynn Webster, and M. Beth Dove. It recommends prescribing a “short-acting opioid” (e.g. morphine, hydromorphone, oxycodone) “when pain can be anticipated,” or a rapid-onset opioid when it cannot. The only examples of rapid-onset opioids then on the market were oral transmucosal fentanyl citrate (*i.e.* Actiq and Fentora). “Both are indicated for treatment of [breakthrough pain] in opioid-tolerant cancer patients *and are frequently prescribed to treat [breakthrough pain] in non-cancer patients as well.*” (emphasis added).

618. *Optimizing Opioid Treatment for Breakthrough Pain* not only deceptively

promoted CEPHALON's drugs for off-label use, but also misleadingly portrayed the risks, benefits, and superiority of opioids for the treatment of chronic pain. For example, the CME misrepresented that Actiq and Fentora would help patients regain functionality by advising that they improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids. The CME also minimized the risks associated with increased opioid doses by explaining that NSAIDs were less effective than opioids for the treatment of breakthrough pain because of their dose limitations, without disclosing the heightened risk of adverse events on high-dose opioids.

619. *Optimizing Opioid Treatment for Breakthrough Pain* was available online and was intended to reach New York and The City of Syracuse prescribers.

620. CEPHALON similarly used an educational grant to sponsor the CME *Breakthrough Pain: Improving Recognition and Management*, which was offered online between March 31, 2008, and March 31, 2009, by Medscape, LLC. The direct result of CEPHALON's funding was a purportedly educational document that echoed CEPHALON's marketing messages: the CME deceptively omitted Actiq's and Fentora's tolerance limitations, cited examples of patients who experienced pain from accidents, not from cancer, and, like CEPHALON's *Optimizing Opioid Treatment* CME, taught that Actiq and Fentora were the only products on the market that would take effect before the breakthrough pain episode subsided. This CME was available online and was intended to reach New York and The City of Syracuse prescribers.

621. Lastly, KOL Dr. Perry Fine authored a CME, sponsored by CEPHALON, titled *Opioid Based Management of Persistent and Breakthrough Pain*, with KOLs Dr. Christine A. Miaskowski and Michael J. Brennan, M.D. CEPHALON paid to have this CME published in

a supplement of Pain Medicine News in 2009. It instructed prescribers that “clinically, broad classification of pain syndromes as either cancer-- or non-cancer--related has limited utility,” and recommended dispensing “rapid onset opioids” for “episodes that occur spontaneously” or unpredictably, including “oral transmucosal fentanyl,” *i.e.*, Actiq, and “fentanyl buccal tablet,” *i.e.*, Fentora, including in patients with chronic non-cancer pain. Dr. Miaskowski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines, that she served on CEPHALON's speakers bureau.¹⁶⁰ Dr. Perry Fine also received funding from CEPHALON for consulting services.

622. *Opioid-Based Management of Persistent and Breakthrough Pain* was available to and was intended to reach New York and The City of Syracuse prescribers.

623. CEPHALON's control over the content of these CMEs is apparent based on its advance knowledge of their content. A December 2005 CEPHALON launch plan set forth key “supporting messages” to position Fentora for its product launch. Among them was the proposition that “15-minute onset of action addresses the unpredictable urgency of BTP.” Years later, the same marketing messages reappeared in the CEPHALON-sponsored CMEs described above. Echoing the CEPHALON launch plan, *Optimizing Opioid Treatment for Breakthrough Pain* stated that “[t]he unpredictability of BTP will strongly influence the choice of treatment” and that Fentora “delivers an onset of analgesia that is similar to [Actiq] at ≤ 15 minutes.” Similarly, *Opioid-Based Management of Persistent and Breakthrough Pain* defined “breakthrough pain” as “unpredictable,” over a table describing both cancer and non-cancer “breakthrough pain.”

624. CEPHALON tracked the effectiveness of its deceptive marketing through third parties, demonstrating that CEPHALON not only planned for but depended upon their activities as a

¹⁶⁰ As described above, 14 out of 21 panel members who drafted the AAPM/APS Guidelines received support from Janssen, Cephalon, Endo, and Purdue.

key element of its marketing strategy.

3. CEPHALON's Deceptive Statements to New York State and City of Syracuse Prescribers and Patients

625. CEPHALON used various measures to disseminate its deceptive statements regarding the risks of off-label use of Actiq and Fentora and the risks, benefits, and superiority of opioids to New York and the City of Syracuse patients and prescribers.

626. CEPHALON targeted New York State and The City of Syracuse prescribers through the use of its sales force, many of which were with prescribers who did not specialize in treating cancer patients. Given Fentora's sole indication for treating cancer pain in opioid-tolerant patients, these physicians were unlikely to prescribe the product for its approved, on-label use.

627. Given that CEPHALON's own studies demonstrated that the overwhelming majority of oncologists diagnose and treat breakthrough cancer pain themselves, CEPHALON knew the only purpose in its representatives meeting with prescribers that did not have cancer-related specialties was to promote off-label use. Based on the uniform and nationwide character of CEPHALON's marketing, CEPHALON's deceptive messages would have been disseminated to New York State and the City of Syracuse prescribers by CEPHALON's sales representatives during these events.

628. Sales representatives, and the misrepresentations on which they were trained, drove significant Fentora sales.

629. CEPHALON's national marketing campaign including the misrepresentations described above were disseminated to New York State and prescribers and consumers. In particular, CEPHALON detailers omitted or minimized the risk of opioid addiction; overstated the benefits of opioids, including by making claims of improved function, and engaged in the

off-label promotion of CEPHALON's drugs for the treatment of chronic non-cancer pain in New York State and the City of Syracuse.

C. JANSSEN

630. JANSSEN promoted its branded opioids, including Duragesic, Nucynta, and Nucynta ER, through its sales representatives and a particularly active speakers program. Deceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms were a foundation of this marketing campaign. JANSSEN also conveyed other misrepresentations as described above, including that its opioids could safely be prescribed at higher doses and were safer than alternatives such as NSAIDs.

631. JANSSEN supplemented these efforts with its own unbranded website, as well as third-party publications and a Front Group website, to promote opioids for the treatment of chronic pain. These materials likewise made deceptive claims about addiction risk, safety at higher doses, and the safety of alternative treatments. They also claimed that opioid treatment would result in functional improvement, and further masked the risk of addiction by promoting the concept of “*pseudoaddiction*”.

632. Based on the highly coordinated and uniform nature of JANSSEN's marketing and as confirmed by verbatim message data and interviews with prescribers, JANSSEN conveyed these deceptive messages to New York State and the City of Syracuse prescribers. The materials that JANSSEN generated in collaboration with third-parties were also distributed or made available in New York and the City of Syracuse. JANSSEN distributed these messages, or facilitated their distribution, in New York and the City of Syracuse with the intent that New York and City of Syracuse prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

1. JANSSEN's Deceptive Direct Marketing

633. JANSSEN joined the other Defendants in propagating deceptive branded marketing that falsely minimized the risks and overstated the benefits associated with the long-term use of opioids to treat chronic pain. Like the other Defendants, JANSSEN sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed identically across the country. These sales representatives were critical in transmitting JANSSEN's marketing strategies and talking points to individual prescribers. In 2011, at the peak of its effort to promote Nucynta ER, JANSSEN spent more than \$90 million on detailing.

634. JANSSEN's designs to increase sales through deceptive marketing are apparent on the face of its marketing plans. For example, although JANSSEN knew that there was no credible scientific evidence establishing that addiction rates were low among patients who used opioids to treat chronic pain, its Nucynta Business Plans indicated that one of the "drivers" to sell more Nucynta among primary care physicians was the "[l]ow perceived addiction and/or abuse potential" associated with the drug. However, there is no evidence that Nucynta is any less addictive or prone to abuse than other opioids, or that the risk of addiction or abuse is low. Similarly, JANSSEN knew that there were severe symptoms associated with opioid withdrawal including, severe anxiety, nausea, vomiting, hallucinations, and delirium, but JANSSEN touted the ease with which patients could come off opioids.

a. JANSSEN'S Deceptive Sales Training

635. JANSSEN's sales force was compensated based on the number of Nucynta prescriptions written in each sales representative's territory. JANSSEN encouraged these sales representatives to maximize sales of Nucynta and meet their sales targets by relying on the false and misleading statements described above.

636. For example, JANSSEN's sales force was trained to trivialize addiction risk. A June 2009 Nucynta training module warns that physicians are reluctant to prescribe controlled substances like Nucynta because of the fear of their patients becoming addicted, but this reluctance is unfounded because "the risks ... are [actually] much smaller than commonly believed." JANSSEN also encouraged its sales force to misrepresent the prevalence of withdrawal symptoms associated with Nucynta. A JANSSEN sales training PowerPoint titled "Selling Nucynta ER and Nucynta" indicated that the "low incidence of opioid withdrawal symptoms" is a "core message" for its sales force. The message was touted at JANSSEN's Pain District Hub Meetings, in which JANSSEN periodically gathered its sales force personnel to discuss sales strategy.

637. This "core message" regarding a lack of withdrawal symptoms runs throughout JANSSEN's sales training materials. For example, JANSSEN's "*Licensed to Sell*" Facilitator's Guide instructs those conducting JANSSEN sales trainings to evaluate trainees, in part, on whether they remembered that "[w]ithdrawal symptoms after abrupt cessation of treatment with NUCYNTA ER were mild or moderate in nature, occurring in 11.8% and 2% of patients, respectively." and whether they were able to "accurately convey" this "core message." JANSSEN further claimed in 2008 that "low incidence of opioid withdrawal symptoms" was an advantage of the tapentadol molecule.

638. Similarly, a Nucynta Clinical Studies Facilitator's Guide instructs individuals training JANSSEN's sales representatives to ask trainees to describe a "key point - that 83% of patients reported no withdrawal symptoms after abruptly stopping treatment without initiating alternative therapy" - "as though he/she is discussing it with a physician."

639. This misrepresentation regarding withdrawal was one of the key messages JANSSEN imparted to employees in the "*Retail ST 101 Training*" delivered to Nucynta sales representatives. It is believed that this training session was attended by sales representatives

from JANSSEN's New York State and the City of Syracuse sales district.

640. Indeed, training modules between 2009 and 2011 instructed training attendees that “most patients [who discontinued taking Nucynta] experienced no withdrawal symptoms” and “[n]o patients experienced moderately severe or severe withdrawal symptoms.” As described below, the *Retail ST 101* Training, upon information and belief, was attended by JANSSEN's New York State and City of Syracuse sales representatives.

641. During the very time JANSSEN was instructing its sales force to trivialize the risks of addiction and withdrawal associated with the use of Nucynta to treat chronic pain, it knew or should have known that, as laid out above, significant numbers of patients using opioids to treat chronic pain experienced issues with addiction. As laid out above, JANSSEN known or should have known that its studies on withdrawal were flawed and created a misleading impression of the rate of withdrawal symptoms and, as a result, the risk of addiction.

642. The compensation to JANSSEN's sales representatives, for the deceptive messages they were promoting to increase sales of Nucynta and Nucynta ER, were directly tied to how many Nucynta and Nucynta ER prescriptions were written by the doctors. These doctors were listed on the quarterly call plans they received from district managers, along with how many doctors or clinics in the assigned zip codes prescribed the drugs that they were being asked to sell. It is believed that family practices and internal medicine doctors made up as many as 80% of the call plan targets for opioids, since, as noted above, these generalists were less knowledgeable about opioids and more likely to fall victim to sales representatives' misrepresentations.

643. It is believed that JANSSEN's sales representative were instructed to push the envelope when selling Nucynta ER by stressing that Nucynta ER didn't hit receptors like other opioids so it was less addictive and had fewer withdrawal issues; to promote Nucynta and Nucynta

ER as a safer alternative to NSAIDs; and, when discussing side effects related to Nucynta and Nucynta ER, to focus only on nausea, itchy skin, and vomiting. It is believed that JANSSEN's sales representatives told physicians that they could prescribe higher doses of Nucynta ER because its mechanism works differently than other opioids; that JANSSEN's opioids can improve their patients' ability to function in their lives and enable them to get off workers' compensation or work pain-free; and, the physicians were provided various books, articles, and pamphlets as handouts by JANSSEN's sales representatives.

644. It is believed that JANSSEN's sales representative were required to attend regional "Plan of Action" meetings several times a year, usually at a hotel or conference facility in New York State. These meetings would include presentations regarding the marketing of JANSSEN's drugs, including Nucynta and Nucynta ER. It is also believed that the various regions would hold weekly Friday calls to make sure that everyone followed the same strategy and talking points. Based on the uniform character of JANSSEN's marketing, New York State and City of Syracuse sales representatives would have received the same sales training and made the same misrepresentations when detailing New York State and City of Syracuse prescribers.

645. It is believed that JANSSEN's sales representatives used a number of KOLs in support of its efforts to sell Nucynta and Nucynta ER. Some of these KOLs were based in New York State and the City of Syracuse and participated in JANSSEN's speaker's bureau. On information and belief, based on the uniform and nationwide character of JANSSEN's marketing, these speakers were trained to deliver the misleading messages described above to prescribers in New York State and the City of Syracuse.

646. It is believed that JANSSEN's sales representatives promoted Nyucynta and Nucynta ER as safe and effective for the long-term treatment of chronic pain and told physicians

that drugs like Tylenol kill the liver, thus, Nucynta and Nucynta ER were cleaner by comparison since they did not attack the organs.

647. It is further believed that JANSSEN's sales representatives were trained to tell prescribers that Nucynta and Nucynta ER did not offer the same euphoric feeling as other opioids; and, that they referred prescribers to a YouTube video that asserted that Nucynta was more difficult to crush than other pills, making it less likely to be abused or diverted. It was common for JANSSEN's sales representatives to downplay the addictive nature of Nucynta and Nucynta ER.

648. The misleading messages and materials JANSSEN provided to its sales force were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included New York State and the City of Syracuse. As described above, JANSSEN's nationwide messages reached New York State and City of Syracuse prescribers in a number of ways, including through its sales force in detailing visits, as well as through websites and ads. They also were delivered to New York and City of Syracuse prescribers by JANSSEN's paid speakers, who were required by JANSSEN policy and by FDA regulations to stay true to JANSSEN's nationwide messaging.

b. JANSSEN's Deceptive Speakers Bureau Programs

649. JANSSEN did not stop at disseminating its misleading messages regarding chronic opioid therapy through its sales force. It also hired speakers to promote its drugs and trained them to make the very same misrepresentations made by its sales representatives.

650. JANSSEN's speakers worked from slide decks - which they were required to present - reflecting the deceptive information about the risks, benefits, and superiority of opioids

outlined above. For example, a March 2011 speaker's presentation titled *A New Perspective for Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability* set out the following adverse events associated with use of Nucynta: nausea, vomiting, constipation, diarrhea, dizziness, headache, anxiety, restlessness, insomnia, myalgia, and bone pain. It completely omitted the risks of misuse, abuse, addiction, hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and other known, serious risks associated with chronic opioid therapy. The presentation also minimized the risks of withdrawal by stating that "more than 82% of subjects treated with tapentadol IR reported no opioid withdrawal symptoms."

651. An August 2011 speaker's presentation titled *New Perspectives in the Management of Moderate to Severe Chronic Pain* contained the same misleading discussion of the risks associated with chronic opioid therapy. It similarly minimized the risks of withdrawal by reporting that 86% of patients who stopped taking Nucynta ER "abruptly without initiating alternative opioid therapy" reported no withdrawal symptoms whatsoever.

652. The same deceptive claims regarding the risks of adverse events and withdrawal appeared in a July 2012 speaker's presentation titled *Powerful Pain Management: Proven Across Multiple Acute and Chronic Pain Models*. These speakers were part of JANSSEN's nationwide marketing efforts.

c. JANSSEN's Deceptive Unbranded Advertising

653. JANSSEN was aware that its branded advertisements and speakers' programs would face regulatory scrutiny that would not apply to its unbranded materials, so JANSSEN also engaged in direct, unbranded marketing.

654. One such unbranded project was JANSSEN's creation and maintenance of *Prescriberesponsibly.com* (last updated July 2, 2015), which was a website aimed at prescribers

and patients claiming that concerns about opioid addiction are “overstated.” A disclaimer at the bottom of the website states that the “site is published by JANSSEN Pharmaceuticals, Inc., which is solely responsible for its content.” This website was available to and intended to reach New York and City of Syracuse area prescribers and patients.

2. JANSSEN’s Deceptive Third-Party Statements

655. JANSSEN’s efforts were not limited to directly making misrepresentations through its sales force, speaker’s bureau, and website. To avoid regulatory constraints and give its efforts and appearance of independence and objectivity, JANSSEN obscured its involvement in certain of its marketing activities by “collaborat[ing] with key patient advocacy organizations” to release misleading information about opioids.

a. AAPM and AGS - Finding Relief: Management for Older Adults

656. JANSSEN worked with AAPM and AGS to create a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009). In doing so, JANSSEN contracted with a medical publishing firm, Conrad & Associates, LLC. The content was drafted by a writer (“Medical Writer X”) hired by Conrad & Associates and funded by JANSSEN. These materials were reviewed, in detail, by JANSSEN’s medical-legal review team, which conducted detailed reviews and gave him editorial feedback on his drafts, which was adopted in the published version.

657. Medical Writer X understood, without being explicitly told, that since his work was funded and reviewed by JANSSEN, the material he was writing should aim to promote the sale of more drugs by overcoming the reluctance to prescribe or use opioids to treat chronic pain. He knew that the publication was undertaken in connection with the launch of a new drug and was part of its promotional effort. Medical Writer X knew of the drug company sponsoring the publication,

and he would go to the company's website to learn about the drug being promoted. He also knew that his clients - including JANSSEN - would be most satisfied with his work if he emphasized that: (a) even when used long-term, opioids are safe and the risk of addiction is low; (b) opioids are effective for chronic pain; and (c) opioids are under-prescribed because doctors are hesitant, confused, or face other barriers.¹⁶¹

658. *Finding Relief* is rife with the deceptive content described above. *Finding Relief* misrepresents that opioids increase function by featuring a man playing golf on the cover and listing examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). *Finding Relief's* functional claims are textbook examples of Defendants' use of third parties to disseminate messages the FDA would not allow them to say themselves. Compare, e.g.:

Branded Advertisement that Triggers an FDA Warning Letter (2008)¹⁶²

Improvements in Daily Activities Includes:

- Walking on a Flat Surface
- Standing or sitting
- Climbing stairs
- Getting in and out of bed or bath
- Ability to perform domestic duties

With:

¹⁶¹ Medical Writer X now acknowledges that the lists of adverse effects from chronic opioid use in the publications he authored, which excluded respiratory depression, overdose, and death and minimized addiction, were, "ridiculous" and "prime examples" of leaving out facts that the pharmaceutical company sponsors and KOLs knew at the time were true. His writings repeatedly described the risk of addiction as low. Medical Writer X stated that he understood that the goal was to promote opioids, and as a result, discussing addiction would be counterproductive.

¹⁶² This advertisement drew an FDA Warning Letter dated March 24, 2008. Though the advertisement was by drug company King, it is used to here to demonstrate the types of claims that the FDA regarded as unsupported.

Seemingly Independent Publication: “Finding Relief: Pain Management for Older Adults” (Final Authority, Janssen 2009)

Your recovery will be measured by how well you reach functional goals such as:

- Sleeping without waking from pain
- Walking more, or with less pain
- Climbing stairs with less pain
- Returning to work
- Enjoying recreational activities
- Having sex
- Sleeping in your own bed

659. *Finding Relief* also trivialized the risks of addiction describing a “myth” that opioids are addictive, and asserting as fact that “[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.” (emphasis added).

660. *Finding Relief* further misrepresented that opioids were safe at high doses by listing dose limitations as “disadvantages” of other pain medicines but omitting any discussion of risks from increased doses of opioids. The publication also falsely claimed that it is a “myth” that “opioid doses have to be bigger over time.”

661. Finally, *Finding Relief* deceptively overstates the risks associated with alternative forms of treatment. It juxtaposes the advantages and disadvantages of NSAIDs on one page, with the “myths/facts” of opioids on the facing page. The disadvantages of NSAIDs are described as involving “stomach upset or bleeding,” “kidney or liver damage if taken at high doses for a long time,” “adverse reactions in people with asthma,” and “increase[d]... risk of heart attack and stroke.” Conversely, the only effects of opioids listed by *Finding Relief* are “upset stomach or sleepiness,” which the brochure claims will go away, and constipation. The guide never mentions addiction, overdose, abuse, or other serious side effects of opioids.

662. JANSSEN was not merely a passive sponsor of Finding Relief. Rather, JANSSEN

exercised control over its content and provided substantial assistance to AGS and AAPM to distribute it. A "Copy Review Approval Form" dated October 22, 2008, indicates that key personnel from JANSSEN's Advertising & Promotion, Legal, Health Care Compliance, Medical Affairs, Medical Communications, and Regulatory Departments reviewed and approved Finding Relief. All six JANSSEN personnel approving the publication checked the box on the approval form indicating that Finding Relief was "Approved with Changes." After the publication was modified at the behest of JANSSEN personnel, JANSSEN paid to have its sales force distribute thousands of copies of Finding Relief in New York State and the City of Syracuse and throughout the nation. Thus, Finding Relief is considered labeling for JANSSEN's opioids within the meaning of 21 C.F.R. § 1.3(a).

663. AAPM purchased and distributed copies of *Finding Relief* to all of its members, including, upon information and belief, those who reside in New York State and the City of Syracuse New York. According to AAPM's website, membership in their organization "is open to physicians (i.e., doctors of medicine or doctors of osteopathy) who have an unrestricted license to practice **medicine in the United States or Canada**. These members spend a significant portion of their professional activities within the field of Pain Medicine or related disciplines."

664. *Finding Relief's* author, Medical Writer X, later said it was clear, from his perch at the intersection of science and marketing, that the money paid by drug companies to the KOLs and professional and patient organizations with which he worked distorted the information provided to doctors and patients regarding opioids. The money behind these and many other "educational" efforts also, he believes, led to a widespread lack of skepticism on the part of leading physicians about the hazards of opioids. It also led these physicians to accept without adequate scrutiny published studies that, while being cited to support the safety of opioids, were, in fact, of such poor methodological quality that they would not normally be accepted as adequate scientific evidence.

b. AGS - Misleading Medical Education

665. JANSSEN also worked with AGS on another project - AGS's CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. As described above, these guidelines falsely claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse" when the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that "[a]ll patients with moderate to severe pain ... should be considered for opioid therapy (low quality of evidence, strong recommendation)." Based on JANSSEN's control over AGS's *Finding Relief*, JANSSEN also would have exercised control over this project as well.

c. APF

666. JANSSEN also worked with APF to carry out its deceptive marketing campaign, and the firm enlisted APF as part of an effort to "draft media materials and execute [a] launch plan for JANSSEN's drugs at an upcoming meeting of the AAPM. JANSSEN also drew on APF publication to corroborate claims in its own marketing materials and its sales training. JANSSEN personnel participated in a March 2011 call with APF's "Corporate Roundtable," in which they worked with APF and drug company personnel to develop strategies to promote chronic opioid therapy. In particular, APF personnel spoke with JANSSEN employees, who "shar[ed] expertise from within their company for [a] public awareness campaign."

667. Their joint work on the "Corporate Roundtable" demonstrates the close collaboration between JANSSEN and APF in promoting opioids for the treatment of chronic pain. APF President Will Rowe also reached out to Defendants - including JANSSEN - rather than his own staff to identify potential authors to draft an answer to an article critical of opioids that appeared in the *Archives of Internal Medicine* in 2011. Additional examples of APF's

collaboration with JANSSEN are laid out below:

i. Let's Talk Pain

668. Most prominent among these efforts was the *Let's Talk Pain* website, JANSSEN sponsored *Let's Talk Pain* in 2009, acting in conjunction with APS, American Academy of Pain Management, and American Society of Pain Management Nursing, whose participation in the website JANSSEN financed and orchestrated.

669. JANSSEN exercised substantial control over the content of the *Let's Talk Pain* website. JANSSEN's internal communications always referred to *Let's Talk Pain* as promoting tapentadol, the molecule it sold as Nucynta and Nucynta ER. JANSSEN regarded *Let's Talk Pain* in addition to the aforescribed website, *Prescriberresponsibly.com*, as integral parts of Nucynta's launch:



JANSSEN documents reveal that JANSSEN's personnel viewed APF and AAPM as "coalition members in the fight to increase market share.

670. To this end, JANSSEN and APF entered into a partnership to "keep pain and the importance of responsible pain management top of mind" among prescribers and patients. They agreed to work to reach "target audiences" that included patients, pain management physicians, primary care physicians, and KOLs. One of the roles JANSSEN assumed in the process was to

“[r]eview, provide counsel on, and approve materials.” JANSSEN did in fact review and approve material for the Let's Talk Pain website, as evidenced by the following edits by a JANSSEN executive to the transcript of a video that was to appear on the site:

<div style="border: 1px solid black; border-radius: 10px; padding: 2px; width: fit-content;">edit out of video</div> <div style="margin-top: 10px;"> <div style="border-left: 1px solid black; height: 100px; position: relative;"> <div style="position: absolute; top: 0; left: -10px;">2</div> <div style="position: absolute; top: 20px; left: -10px;">3</div> <div style="position: absolute; top: 40px; left: -10px;">4</div> <div style="position: absolute; top: 60px; left: -10px;">5</div> <div style="position: absolute; top: 80px; left: -10px;">6</div> </div> </div>	<p>Shaffer: This is what has allowed me to continue to function. It is what allowed me to have somewhat of a normal life, is the opioids. But, and I do have a concern about the risk, but I also know that if I take them as directed by my physician, and I let them know of any adverse reactions that I might feel promptly, that I'm safe.</p> <p>Anderson: And that is true. The job of the physician that's prescribing</p>
---	--

The final version of the video on *Let's Talk Pain* omitted the stricken language above.

671. This review and approval authority extended to the *Let's Talk Pain* website. Emails between JANSSEN personnel and a consultant indicate that, even though the *Let's Talk Pain* website was hosted by APF, JANSSEN had approval rights over its content. Moreover, emails describing JANSSEN's review and approval rights related to *Let's Talk Pain* indicate that this right extended to "major changes and video additions."

672. As a 2009 JANSSEN memo conceded, “[t]he *Let's Talk Pain* coalition is sponsored by PriCara, a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.” and “[t]he Coalition and PriCara **maintain editorial control of all *Let's Talk Pain* materials and publications**” (emphasis added).

673. A 2011 Consulting Agreement between JANSSEN and one of APF's employees, related to the dissemination of national survey data, demonstrated the near-total control JANSSEN was empowered to exercise over APF in connection with the *Let's Talk Pain* website, including in requiring APF to circulate and post JANSSEN's promotional content. The agreement required APF

to “participate in status calls between JANSSEN, APF, AAPM, ASPM, and Ketchum as requested by JANSSEN” and required APF to “respond to requests to schedule status calls **within 48 hours** of the request” (emphasis in original). APF was also required to “[r]eview and provide feedback to media materials, including a press release, pitch email, a key messages document, and social media messages, **within one week** of receipt” (emphasis in original).

674. The agreement further required APF to provide a summary of the survey results in APF’s PAIN MONITOR e-newsletter, post a link to the survey on APF’s Facebook page, “[s]hare information with any media contacts with whom APF has existing relationships to promote the announcement of the national survey findings,” identify at least two patient spokespersons to talk about the survey data, and include the survey results in “any future APF materials, as appropriate.” Tellingly, “any ideas made or conceived by [APF] in connection with or during the performance” of the Agreement “shall be the property of, and belong to [Janssen].”

675. JANSSEN also exercised its control over *Let’s Talk Pain*. JANSSEN was able to update the *Let’s Talk Pain* website to describe its corporate restructuring and JANSSEN personnel asserted their control over “video additions” by reviewing and editing the interview touting the functional benefits of opioids described above. Given its editorial control over the content of *Let’s Talk Pain*, JANSSEN was at all times fully aware of, and full involved in shaping, the website’s content. JANSSEN does not publicly identify its role in creating *Let’s Talk Pain*’s content. Instead, *Let’s Talk Pain* represents that “coalition members” develop the content that appears on the website and lists JANSSEN as the only sponsor of that coalition.

676. *Let’s Talk Pain* contained a number of the misrepresentations as outlined herein.

677. For example, *Let’s Talk Pain* misrepresented that the use of opioids for the treatment of chronic pain would lead patients to regain functionality. *Let’s Talk Pain* featured an

interview claiming that opioids allowed a patient to “continue to function.” This video is still available today on *YouTube.com* and is accessible to New York and City of Syracuse prescribers and patients.

678. *Let’s Talk Pain*, in 2009, also promoted the concept of “pseudoaddiction”, which it described as patient behaviors that may occur when “pain is under-treated” but differs “from true addiction because such behaviors can be resolved with effective pain management” (emphasis added). *Let’s Talk Pain* was available to and was intended to reach New York State and City of Syracuse patients and prescribers.

ii. Exit Wounds

679. JANSSEN also engaged in other promotional projects with and through APF. One such project was the publication and distribution of *Exit Wounds*, which deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Exit Wounds* was drafted by “Medical Writer X.” It is fully representative of his work on behalf of drug companies.

680. JANSSEN gave APF substantial assistance in distributing *Exit Wounds* in New York and City of Syracuse and throughout the nation by providing grant money and other resources. It is believed that APF mailed copies of *Exit Wounds* to Wounded Heroes organizations in New York State and the City of Syracuse that support injured men and women who have served the United States in Iraq, Afghanistan and around the world. Unfortunately, by distributing *Exit Wounds* to Wounded Hero’s organizations’ members, it distributed Defendants’ deceptive statements about the appropriateness of opioid therapy to treat chronic pain.

3. JANSSEN’s Deceptive Statements to New York State and City of Syracuse Prescribers and Patients

681. JANSSEN also directed the misstatements described above to New York and City of Syracuse prescribers, including through CMEs, its sales force, and recruited physician speakers.

a. JANSSEN's Deceptive Medical Education Programs in New York State

682. JANSSEN sponsored CMEs and talks attended by New York State and City of Syracuse prescribers.

683. Speakers on JANSSEN's bureau were among the more prolific prescribers of JANSSEN's opioids. They received thousands of dollars in speakers' fees and wrote thousands of dollars in prescriptions for JANSSEN opioids, including claims from Nucynta and Nucynta ER. These doctors were trained by JANSSEN and therefore exposed to the same misrepresentations disseminated to other doctors. Further, the benefits of speaking on behalf of JANSSEN gave them a powerful incentive to continue to prescribe JANSSEN's opioids.

684. JANSSEN created a "Meetings Direct" program that were talks billed as a "peer-to-peer" program aimed to influence physicians and to "[e]stablish ... Nucynta ER as [the] new standard ... in moderate-to-severe ... pain management." Based on the uniform and nationwide character of JANSSEN's marketing campaign, the speakers at these events would deliver talks from slide decks provided by JANSSEN, consistent with their key deceptive messages.

b. JANSSEN's Deceptive Detailing Practices in New York State

685. The experiences of specific prescribers confirm both that JANSSEN's national marketing campaign included the misrepresentations described above, and that the company disseminated these same misrepresentations to New York State and City of Syracuse prescribers and consumers. In particular, these prescriber accounts reflect that JANSSEN detailers claimed that Nucynta was "not an opioid" because it worked on an "alternate receptor";¹⁶³ claimed that JANSSEN's drugs would be less problematic for patients because they had anti-abuse properties

¹⁶³ The FDA-approved labels for both Nucynta and Nucynta ER describe the tapentadol molecule as "opioid agonist and a Schedule II controlled substance that can be abused in a manner similar to other opioid agonists, legal or illicit."

and were "steady state"; claimed that patients on JANSSEN's drugs were less susceptible to withdrawal; omitted or minimized the risk of opioid addiction; claimed or implied that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

686. JANSSEN sales representatives promoting Duragesic made claims to New York State and City of Syracuse prescribers that Duragesic improves physical function. They also misrepresented the likelihood of abuse associated with JANSSEN's drugs by falsely stating that Duragesic had anti-abuse properties. Nucynta and Nucynta ER sales representatives repeatedly promoted these drugs as less addictive than other opioids, and even described Nucynta as "not an opioid" and that Nucynta was "non-opioid yet opioid like".

D. DEPOMED

687. DEPOMED promoted its branded opioids, including Lazanda, Nucynta, and Nucynta ER, through its sales representatives and a particularly active speakers program. Deceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms were a foundation of this marketing campaign. DEPOMED also conveyed other misrepresentations as described above, including that its opioids could safely be prescribed at higher doses and were safer than alternatives such as NSAIDs.

688. DEPOMED supplemented these efforts with its own unbranded website, as well as third-party publications and a Front Group website, to promote opioids for the treatment of chronic pain. These materials likewise made deceptive claims about addiction risk, safety at higher doses, and the safety of alternative treatments.

689. Based on the highly coordinated and uniform nature of DEPOMED's marketing and as confirmed by verbatim message data and interviews with prescribers, DEPOMED conveyed

these deceptive messages to New York State, Onondaga County and/or City of Syracuse prescribers. The materials that DEPOMED generated in collaboration with third-parties were also distributed or made available in New York State, Onondaga County and City of Syracuse. DEPOMED distributed these messages, or facilitated their distribution, in New York State, Onondaga County and/or the City of Syracuse with the intent that their prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

1. DEPOMED's Deceptive Direct Marketing

690. DEPOMED joined the other Defendants in propagating deceptive branded marketing that falsely minimized the risks and overstated the benefits associated with the long-term use of opioids to treat chronic pain. Like the other Defendants, DEPOMED's sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed identically across the country. These sales representatives were critical in transmitting DEPOMED's marketing strategies and talking points to individual prescribers.

691. DEPOMED's designs to increase sales through deceptive marketing are apparent on the face of its marketing plans. For example, although DEPOMED knew that there was no credible scientific evidence establishing that addiction rates were low among patients who used opioids to treat chronic pain, its Nucynta Business Plans indicated that one of the "drivers" to sell more Nucynta among primary care physicians was the "[l]ow perceived addiction and/or abuse potential" associated with the drug. However, there is no evidence that Nucynta is any less addictive or prone to abuse than other opioids, or that the risk of addiction or abuse is low. Similarly, DEPOMED knew that there were severe symptoms associated with opioid withdrawal including, severe anxiety, nausea, vomiting, hallucinations, and delirium, but DEPOMED touted the ease with which patients could come off opioids.

a. DEPOMED's Deceptive Sales Training

692. DEPOMED's sales force, upon information and belief, was compensated based on the number of Nucynta prescriptions written in each sales representative's territory. DEPOMED encouraged these sales representatives to maximize sales of Lazanda and Nucynta and meet their sales targets by relying on the false and misleading statements described above.

693. For example, DEPOMED's sales force was trained to trivialize addiction risk. During the very time DEPOMED was instructing its sales force to trivialize the risks of addiction and withdrawal associated with the use of Lazanda and/or Nucynta to treat chronic pain, it knew or should have known that, as laid out above, significant numbers of patients using opioids to treat chronic pain experienced issues with addiction.

694. The compensation to DEPOMED's sales representatives, upon information and belief, for the deceptive messages they were promoting to increase sales of Lazanda, Nucynta and Nucynta ER, were directly tied to how many of these prescriptions were written by the doctors. These doctors were listed on the quarterly call plans they received from district managers, along with how many doctors or clinics in the assigned zip codes prescribed the drugs that they were being asked to sell. It is believed that family practices and internal medicine doctors made up a large percentage of the call plan targets for opioids, since, as noted above, these generalists were less knowledgeable about opioids and more likely to fall victim to sales representatives' misrepresentations.

695. It is believed that DEPOMED's sales representative were instructed to push the envelope when selling its prescription medications, such as Nucynta ER by stressing that Nucynta ER didn't hit receptors like other opioids so it was less addictive and had fewer withdrawal issues; to promote Nucynta and Nucynta ER as a safer alternative to NSAIDs; and, when discussing side

effects related to Nucynta and Nucynta ER, to focus only on nausea, itchy skin, and vomiting. It is believed that DEPOMED's sales representatives told physicians that they could prescribe higher doses of Nucynta ER because its mechanism works differently than other opioids; that DEPOMED's opioids can improve their patients' ability to function in their lives and enable them to get off workers' compensation or work pain-free; and, the physicians were provided various books, articles, and pamphlets as handouts by DEPOMED's sales representatives.

696. It is believed that DEPOMED's sales representative were required to attend regional "Plan of Action" meetings several times a year, usually at a hotel or conference facility in New York State. These meetings would include presentations regarding the marketing of DEPOMED's drugs, including Lazanda, Nucynta and Nucynta ER. Based on the uniform character of DEPOMED's marketing, New York State, Onondaga County and/or City of Syracuse sales representatives would have received the same sales training and made the same misrepresentations when detailing New York State, Onondaga County and/or City of Syracuse prescribers.

697. It is believed that DEPOMED's sales representatives used a number of KOLs in support of its efforts to sell Nucynta and Nucynta ER. Some of these KOLs were based in New York State, Onondaga County and/or City of Syracuse and participated in DEPOMED's speaker's bureau. On information and belief, based on the uniform and nationwide character of DEPOMED's marketing, these speakers were trained to deliver the misleading messages described above to prescribers in New York State, Onondaga County and/or the City of Syracuse.

698. It is believed that DEPOMED's sales representatives promoted Lazanda, Nucynta and Nucynta ER as safe and effective for the long-term treatment of chronic pain and told physicians that drugs like Tylenol kill the liver, thus, its medications were cleaner by

comparison since they did not attack the organs.

699. It is further believed that DEPOMED's sales representatives were trained to tell prescribers that its medications such as Nucynta and Nucynta ER did not offer the same euphoric feeling as other opioids. It was common for DEPOMED's sales representatives to downplay the addictive nature of its medications such as Nucynta and Nucynta ER.

700. The misleading messages and materials DEPOMED provided to its sales force were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included New York State, Onondaga County and the City of Syracuse.

701. As described above, DEPOMED's nationwide messages reached New York State, Onondaga County and/or the City of Syracuse prescribers in a number of ways, including through its sales force in detailing visits, as well as through websites and ads. They were also delivered to New York State, Onondaga County and/or the City of Syracuse prescribers by DEPOMED's paid speakers, who were required by DEPOMED policy and by FDA regulations to stay true to DEPOMED's nationwide messaging.

b. DEPOMED's Deceptive Speakers Bureau Programs

702. DEPOMED did not stop at disseminating misleading messages regarding chronic opioid therapy through its sales force. It also hired speakers to promote its drugs and trained them to make the very same misrepresentations made by its sales representatives.

703. In yet another attempt to increase revenue and market share, DEPOMED paid speaker fees to physicians to induce them to write Lazanda or Nucynta prescriptions that were reimbursed through third party payor health plans.

704. As a façade for this arrangement, DEPOMED conducted speaker programs that

were actually vehicles for paying monies to physicians under the guise of honoraria. These financial benefits were offered with the understanding that, in exchange, the physicians would preferentially prescribe or indicate the use of Lazanda or Nucynta to treat their patients.

705. Through DEPOMED's speaker programs, physician speakers were ostensibly paid to speak at ongoing speaking engagement events to educate other doctors and health care professionals about Lazanda or Nucynta. In practice, however, DEPOMED's speaker program exists to induce physicians to increase the quantity of Lazanda or Nucynta prescriptions they write.

706. Specifically, DEPOMED offered ongoing speaker positions to pain management physicians, whom it deemed "high writers" – physicians writing five or more prescriptions per month. These speaking arrangements usually consisted of dinners with colleagues. Significantly, these speaking engagements never included physicians who treat cancer patients.

707. The qualifications of the physicians hired as speakers by DEPOMED demonstrate that its speaker program was nothing more than a mechanism to facilitate kickbacks in return for writing Lazanda or Nucynta prescriptions. The criteria used to determine which physicians to offer speaker positions to depended primarily upon the volume of Lazanda or Nucynta prescriptions written.

708. As Lazanda's indicated use is pain management for cancer patients, it would be reasonable to expect that the physicians DEPOMED selected to educate and inform other physicians and health care professionals about the drug would be oncologists, or otherwise have at least some level of expertise in dealing with cancer patients. And yet, DEPOMED did not condition its selection of speakers on whether they had a pedigree that included cancer treatment. Instead, DEPOMED focused solely on those physicians who wrote the most prescriptions for Lazanda.

709. And, because DEPOMED's focus was on rewarding high writers and not on

actually educating, DEPOMED did not screen speakers based on academic or clinical accomplishments. Where a speaker's curriculum vitae ("CV") was relatively unspectacular, DEPOMED would simply not provide it to the speaker's "audience." In one example, a high writer/speaker's CV was never circulated before his speaking engagements because he attended Guadalajara Medical School, a school that was not prestigious enough.

710. In addition, DEPOMED's speaker program also demonstrated its intent to induce physicians to preferentially prescribe or indicate Lazanda to their patients. The speakers selected by DEPOMED were incapable of prescribing (or at best, highly unlikely to prescribe) Lazanda for its indicated use because their patient populations did not have cancer. Moreover, DEPOMED selected speakers who were high writers of Lazanda and attempted to conceal the fact that they had virtually no experience treating cancer patients. Indeed, DEPOMED's selection of non-cancer treating physicians, as well as its attempt to conceal this fact, demonstrates that DEPOMED intended and did, in fact, utilize its speaker program to fraudulently induce Lazanda prescriptions by providing illegal compensation to prescribing physicians.

c. DEPOMED's Advertisements Contain Misleading Safety Messages

711. Likewise, on a website that was designed to market Nucynta, DEPOMED promoted Nucynta ER as more tolerable because of fewer "discontinuation rates due to treatment-emergent adverse events." The website set forth a number of treatment emergent adverse events and how they compare to one competitor, oxycodone. The website also claimed that Nucynta ER is safe because only 4.8% of Nucynta ER-treated patients experienced mild or moderate withdrawal. However, none of this appears on the FDA-approved label for Nucynta.

d. DEPOMED's Deceptive Unbranded Advertising

712. DEPOMED was aware that its branded advertisements and speakers' programs

would face regulatory scrutiny that would not apply to its unbranded materials, so DEPOMED also engaged in direct, unbranded marketing, as is set forth throughout this Complaint.

2. DEPOMED's Deceptive Third-Party Statements

713. DEPOMED's efforts were not limited to directly making misrepresentations through its sales force, speaker's bureau, and website. To avoid regulatory constraints and give its efforts and appearance of independence and objectivity, DEPOMED obscured its involvement in certain of its marketing activities by "collaborat[ing] with key patient advocacy organizations" to release misleading information about opioids.

714. In February of 2012, Sen. Claire McCaskill released the findings of an 11-month opioid probe, which revealed that the manufacturing industry contributed millions of dollars to advocacy groups that backed wide use of opioid medications. The report outlines contributions by DEPOMED (as well as PURDUE, JANSSEN and INSYS) to 14 patient organizations and affiliated individuals between 2012 and 2017. According to the report, Defendants backing the groups "amplified messages favorable to increased opioid use". DEPOMED made more than \$1 million in payments to the groups, according to Senator McCaskill's report (PURDUE made \$4 million plus in payments to the groups, INSYS' \$3 million plus in contributions. JANSSEN \$465,000 plus in contributions to the groups during the period) This report was published just days after PURDUE said it would stop marketing OxyContin and other opioid pain meds to physicians. Additionally, doctors affiliated with the groups have accepted more than \$1.6 million in payments from the companies since 2013, according to Senator McCaskill's report.¹⁶⁴

¹⁶⁴ *Breaking: Millions in Payments among findings of McCaskill opioid investigation into ties between manufacturers and third party advocacy groups, U.S. Senate Committee Homeland Security and Government Affairs, February 12, 2018, <https://www.hsgac.senate.gov/media/minority-media/breaking-millions-in-payments-among-findings-of-mccaskill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-groups->*

	2012	2013	2014	2015	2016	2017	Total
Purdue	\$824,227.86	\$973,328.00	\$812,451.95	\$935,344.00	\$558,067.52	\$50,135.00	\$4,153,554.33
Janssen	\$239,902.85 ³⁴	\$99,250.00	\$126,000.00				\$465,152.85
Depomed	\$73,080.00	\$135,300.00	\$113,600.00	\$350,000.00	\$318,257.47	\$80,879.48	\$1,071,116.95
Insys	\$14,040.00	\$68,000.00	\$34,200.00	\$530,025.00		\$2,500,000.00	\$3,146,265.00
Mylan				\$15,000.00	\$2,500.00	\$2,750.00	\$20,250.00
Total	\$1,151,250.71	\$1,275,878.00	\$1,086,251.95	\$1,830,369.00	\$878,824.99	\$2,633,764.48	\$8,856,339.13

A table from Sen. McCaskill's report shows drugmaker contributions to patient groups by year.

715. The report's key findings include: (1) Contributions from five leading opioid manufacturers of nearly \$9 million to 14 third party advocacy organizations over a five year period. (2) Additional payments of \$1.6 million from the five manufacturers to physicians affiliated with these groups between 2013 and the present. (3) Several of the groups profiled received the majority of their outside contributions and grants for certain years between 2012 and 2017 from opioid manufacturers. (4) Initiatives from the groups in this report often echoed and amplified messages favorable to increased opioid use - and ultimately, the financial interests of opioid manufacturers. (5) These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for over prescription and misbranding. For example: According to lawsuits filed across the country, the American Academy of Pain Medicine, which received almost \$1.2 million from the five manufacturers under investigation between 2012 and 2017, issued a 2009 patient guide stating that "*opioids are rarely addictive when used properly for the management of chronic pain.*" (6) The Washington Legal Foundation criticized 2016 Centers for Disease Control and Prevention (CDC) prescribing guidelines that recommended limits on opioid prescriptions for chronic pain - the first national standards for prescription opioids and a key federal response to the ongoing epidemic - as procedurally flawed and tainted by bias - and also received \$500,000 from Purdue Pharma between 2012 and 2016. Notably, a majority of the

groups profiled in McCaskill's report strongly criticized these guidelines. (7) The Academy of Integrative Pain Management, which received over \$1.2 million from the five manufacturers, has partnered with the American Cancer Society Cancer Action Network on opioid-related lobbying in 18 states as of 2016, including efforts to block limits on opioid prescribing. *"The fact that these same manufacturers provided millions of dollars to the groups described [in this report] suggests, at the very least, a direct link between corporate donations and the advancement of opioids-friendly messaging. By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic,"* Senator McCaskill's report states.¹⁶⁵

716. McCaskill's report also details a troubling lack of transparency surrounding the advocacy organizations. Due to their classification under the U.S. tax code, the groups profiled in the report have no obligation to disclose their donors publicly. As a result, each group maintains different levels of transparency regarding its financial connections to the pharmaceutical industry and has no obligation to publicly disclose their funding sources. These organizations have the ability to selectively disclose donors, donations, and other support - or no information at all. No organization profiled in McCaskill's report provides an online list linking donors, their specific donations, and the projects or events benefiting from each donation for each of the years between 2012 and 2017.

McCaskill said, *"The financial relationships between these groups and opioid manufacturers should be clear to the general public". "We passed a law ensuring the public had information on payments to doctors by pharmaceutical companies, and I can't imagine why the same shouldn't be done in this space."*¹⁶⁶

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

3. DEPOMED's Deceptive Statements to New York State and City of Syracuse Prescriber and Patients

717. DEPOMED also directed the misstatements described above to New York and City of Syracuse prescribers, including through CMEs, its sales force, and recruited physician speakers.

a. DEPOMED's Deceptive Medical Education Programs in New York State

718. DEPOMED sponsored CMEs and talks attended by New York State, Onondaga County and/or City of Syracuse prescribers.

719. Speakers on DEPOMED's bureau were among the more prolific prescribers of DEPOMED's opioids. They received thousands of dollars in speakers' fees and wrote thousands of dollars in prescriptions for DEPOMED opioids, including claims from Nucynta and Nucynta ER. These doctors were trained by DEPOMED and therefore exposed to the same misrepresentations disseminated to other doctors. Further, the benefits of speaking on behalf of DEPOMED gave them a powerful incentive to continue to prescribe DEPOMED's opioids.

b. DEPOMED's Deceptive Detailing Practices in New York State

720. The experiences of specific prescribers confirm both that DEPOMED's national marketing campaign included the misrepresentations described above, and that the company disseminated these same misrepresentations to New York State, Onondaga County and/or City of Syracuse prescribers and consumers. In particular, these prescriber accounts reflect that DEPOMED detailers claimed that Nucynta was "not an opioid" because it worked on an "alternate receptor";¹⁶⁷ claimed that DEPOMED's drugs would be less problematic for patients because they had anti-abuse properties and were "steady state"; claimed that patients on

¹⁶⁷ The FDA-approved labels for both Nucynta and Nucynta ER describe the tapentadol molecule as "opioid agonist and a Schedule II controlled substance that can be abused in a manner similar to other opioid agonists, legal or illicit."

DEPOMED's drugs were less susceptible to withdrawal; omitted or minimized the risk of opioid addiction; claimed or implied that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

721. DEPOMED has, since at least October 2011, engaged in unsafe and/or unapproved marketing of Lazanda and (with the acquisition from Janssen in January 2015) of Nucynta and Nucynta ER.

i. DEPOMED Sales Representatives Promoted Lazanda for Unsafe and Unapproved Uses

722. Lazanda is only indicated “for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.” Despite the drug’s explicit limitation, DEPOMED actively promoted Lazanda to physicians who do not treat cancer patients. Not only did DEPOMED instruct sales representatives to promote Lazanda to non-cancer treating physicians, the Company also discouraged sales representatives from marketing the drug to physicians treating cancer patients, even if the sales representatives were successful in gaining these doctors' business.

723. When it launched Lazanda in 2011, the Company’s management, from the start, disregarded the FDA’s limitations concerning Lazanda's usage, instructing its sales representatives to target pain management physicians, particularly those who historically wrote large numbers of opioid drugs and Lazanda-like drugs.

724. Sales representatives were pressured to target pain management physicians. Area managers at DEPOMED regularly supplied sales representatives with lists of target physicians containing few, if any, physicians treating cancer patients. Of the typical call list containing approximately 100 physicians, under five generally treated cancer patients.

725. DEPOMED also strongly discouraged sales representatives from targeting

physicians treating cancer patients. Sales representatives had to “make a case” for using any portion of their allotted marketing money to call on cancer treating physicians. And employees who did call on cancer treating physicians were disciplined.

726. One DEPOMED sales representative, who worked in the Los Angeles area, was chastised by management for targeting, almost exclusively, physicians treating cancer patients despite the fact that he had been very successful in generating business from these physicians. This representative was reprimanded for targeting physicians who could prescribe Lazanda for its indicated use, and was told to stop targeting these physicians, and to think about how well he could be doing if he was targeting potentially higher writers.

727. DEPOMED explicitly told sales representatives to market only to non-cancer treating physicians by their managers, most notably Todd Wittenbach, the company’s then head of sales for the United States.

728. DEPOMED sales representatives were also trained to deal with (rightful) pushback from physicians. For example, when confronted with the common statement from a physician that “it’s extremely rare that we see cancer patients,” DEPOMED trained sales representatives to divert the conversation to the physician's use of other, similar medications. For example, sales representatives were trained to respond by saying “well tell me about your patients taking Actiq,” and then extol the relative benefits of switching those patients to Lazanda.

729. Due to the worsening headwinds within the opioid market, DEPOMED ultimately sold Lazanda to Slán Medicinal Holdings on November 7, 2017.

ii. DEPOMED Sales Representatives Promoted Nucynta and Nucynta ER for Unsafe and Unapproved Uses

730. On April 2, 2015, DEPOMED acquired from Janssen and its affiliates the U.S. rights to the Nucynta franchise of pharmaceutical products for \$1.05 billion in cash. The Nucynta

franchise is an opioid that includes Nucynta ER (tapentadol) extended release tablets indicated for the management of pain, including neuropathic pain associated with diabetic peripheral neuropathy (DPN), severe enough to require daily, around-the-clock, long-term opioid treatment, Nucynta IR (tapentadol), an immediate release version of tapentadol, for management of moderate to severe acute pain in adults, and Nucynta (tapentadol) oral solution, an approved oral form of tapentadol that has not been commercialized.

731. Nucynta's annual sales increased in the U.S. from \$189.9 million in 2015 to approximately \$281.3 million in 2016, quickly becoming DEPOMED's best-selling product. This marked a 48% year-over-year growth in sales of Nucynta in just one year.

732. The marketing strategy causing the astronomical growth in sales, however, was fueled by DEPOMED's illegal practices in connection with its marketing of Nucynta for unsafe and unapproved uses. In particular, DEPOMED promoted the use of opioids for all manner of pain management while downplaying the drug's addictive nature, often promoting the drug as a safer alternative to opioids, despite this not being on the FDA label.

733. Further, DEPOMED promoted an increase in dosage while focusing on family physicians and internal medicine doctors who were less knowledgeable about the dangers of opioids.

734. In February 2017, DEPOMED's former CEO increased its sales force for the specific purpose of targeting primary care physicians.

735. The FDA-approved labels for both Nucynta IR and Nucynta ER describe the tapentadol molecule as "a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone." Nowhere on the FDA-approved label does it say or mention that Nucynta is safer, more tolerable, less abusive, or less addictive than other opioids. Despite this, Nucynta has a long history of its

manufacturer (formerly Janssen, see supra) claiming these benefits in its sales pitches and marketing.

736. Nonetheless, DEPOMED directed its sales representatives to market Nucynta for unsafe and unapproved uses as a safer, less abusive, less addictive opioid that did not create the same euphoric feeling as other opioids, even though this was not on the FDA-approved label.

737. DEPOMED management knew that the FDA-approved label for Nucynta contained no information about it being safer, more tolerable, less addictive, or less abusive than alternative opioids, and knew they could not market Nucynta this way.

738. On a June 23, 2015 investor call, August Moretti, DEPOMED's Senior Vice President and Chief Financial Officer, stated that “[a]lthough not in the label, there’s a very low abuse profile and side effect rate.”

739. Additionally, in a March 14, 2015 presentation at the ROTH Conference, then DEPOMED CEO Schoeneck stated: “The addiction profile is thought to be better. I can’t make a claim around that because we don’t actually have that in the label.” In February 2017, Schoeneck also told investors that DEPOMED was “initiating label enhancement studies, aimed at further differentiating Nucynta by highlighting its respiratory depression and abuse potential profile. These labeling studies will focus on the properties of the tapentadol molecule, and its uniqueness in the pain marketplace.” The purpose of this was to “be able to get it hopefully into the label.”

740. DEPOMED’s marketing push was “Think Differently.” Sales representatives were told that Nucynta is a “safer opioid.” They were told to tell physicians about Nucynta and its value to patients in terms of, among other things, improved safety relative to other opioids on the market.

741. DEPOMED actively targeted primary care physicians with marketing presentations that described Nucynta as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. DEPOMED did not have FDA-approval to market

Nucynta in this manner, and also did not have any independent scientific evidence to support these claims.

742. DEPOMED represented that Nucynta was uniquely positioned to combat the negative public sentiment against Opioids. Former President and CEO James Schoeneck described to investors that Nucynta had *“different properties than the other opioids, particularly when it comes to the kind of activity that the CDC and others are most concerned about” and that there’ll be relatively little impact on [DEPOMED] compared to where some other companies may fall in at.”*

743. DEPOMED knew that it could not promote Nucynta as a safer, less addictive, less abusive opioid that did not have the same euphoric feeling on patients because these properties were not on its FDA-approved label. Despite this knowledge, DEPOMED trained its sales representatives to use these marketing tactics to sell Nucynta, using the same sales team as Janssen had to promote Nucynta, knowing that Janssen was being sued for, among other things, improperly marketing Nucynta.

744. Due to the worsening headwinds within the Opioid market, DEPOMED ultimately entered into a commercialization agreement with Collegium Pharmaceutical, Inc., for the NUCYNTA brand on December 4, 2017.

745. DEPOMED sales representatives promoting their prescription opioid drugs made claims to New York State and City of Syracuse prescribers that their medications improved physical function. They also misrepresented the likelihood of abuse associated with DEPOMED’s drugs by falsely stating that their medications had anti-abuse properties. DEPOMED’s sales representatives repeatedly promoted these drugs as less addictive than other opioids, and even described Nucynta as “not an opioid” and that Nucynta was “non-opioid yet opioid like”.

E. ENDO

746. ENDO promoted its opioids through a full array of marketing channels. The company deployed its sales representatives, paid physician speakers, journal supplements, and advertising in support of its branded opioids, principally Opana and Opana ER. Misleading claims about the purportedly lower abuse potential of Opana ER featured prominently in their campaign. Additionally, ENDO made many other deceptive statements and omissions as described herein. These included deceptive statements about functional improvement, addiction risks, pseudoaddiction, addiction screening tools, and the safety of alternatives to opioids.

747. At the same time, ENDO also relied on a cast of third-party partners to promote the safety, efficacy, and superiority of opioids generally, through a combination of CMEs, websites, patient education pamphlets, and other publications. These materials echoed the misrepresentations described above, and also made deceptive statements about withdrawal symptoms and the safety of opioids at higher doses.

748. Based on the highly coordinated and uniform nature of ENDO's marketing, and as confirmed by verbatim message data and interviews with a sales representative and prescribers, ENDO conveyed these deceptive messages to New York and City of Syracuse prescribers. The materials that ENDO generated in collaboration with third-parties also were distributed or made available in New York State and City of Syracuse. ENDO distributed these messages, or facilitated their distribution, in New York State and City of Syracuse with the intent that their prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

1. ENDO's Deceptive Direct Marketing

749. Like the other Defendants, ENDO used deceptive direct marketing to increase

the sales of its dangerous opioids. As set forth below, ENDO conveyed these deceptive messages in training of its sales force and recruited speakers, who in turn conveyed them to physicians in a misleading journal supplement; and in unbranded advertising.

a. ENDO's Sales Force and Deceptive Sales Training

750. ENDO's promotion of Opana ER relied heavily on in-person marketing, including to New York State and City of Syracuse prescribers. ENDO had an aggressive detailing program, with its sales representatives making thousands of visits to prescribers nationwide to detail Opana ER in the first quarter of 2010 alone. Between 2007 and 2013, ENDO spent between \$3 million and \$10 million each quarter to promote opioids through its sales force.

751. ENDO's sales representatives, like those of the other Defendants, targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales representatives were critical in transmitting ENDO's marketing strategies and talking points to individual prescribers.

752. ENDO specifically directed its sales force to target physicians who would prescribe its drugs to treat chronic pain. For example, an Opana Brand Tactical Plan dated August, 2007 aimed to increase "Opana ER business from [the Primary Care Physician] community" more than 45% by the end of that year. Indeed, ENDO sought to develop strategies that would be most persuasive to primary care doctors and would influence their prescribing behavior through the use of subject matter experts. A February 2011 Final Report on Opana ER Growth Trends, for example, predicted that ENDO's planned "[u]se of Pain Specialists as local thought leaders should affect increased primary care adoption."

753. ENDO trained its sales force to make a number of misrepresentations to

physicians nationwide, including to physicians in New York State and City of Syracuse. ENDO's sales representatives were trained to represent to these prescribers that Opana ER would help patients regain function they had lost to chronic pain; that ENDO opioids had a lower potential for abuse because they were "designed to be crush resistant," even though the "clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER;" and that drug seeking behavior was a sign of undertreated pain rather than addiction.

754. ENDO knew that its marketing repeatedly reached physicians because it tracked their exposure. Internal ENDO documents dated August 23, 2006, demonstrate that the following percentages of physicians would view an ENDO journal insert (or paid supplement) at least 3 times in an 8-month period: 86% of neurologists; 86% of rheumatologists; 85% of oncologists; 85% of anesthesiologists; 70% of targeted primary care physicians; and 76% of Ob/Gyns.

755. ENDO was not only able to reach physicians through its marketing, but also successfully imparted its marketing messages. The company found its promotional materials tripled prescribers' ability to recall the sales message and doubled their willingness to prescribe Opana ER in the future. This was true of the marketing that contained ENDO's deceptions.

756. For example, according to internal ENDO documents, up to 10% of physicians it detailed were able to recall, without assistance, the Opana ER message that it had "Minimal/less abuse/misuse" potential than other drugs. This message was a plain misrepresentation that the use of Opana ER was unlikely to lead to abuse and addiction. Despite Opana ER being classified under Schedule II as a drug with a "high potential for abuse" and consistent with the pattern of misrepresentations described above, the largest single perceived advantage of Opana

ER, according to a survey of ¹⁸⁷ physicians who reported familiarity with the drug, was "perceived low abuse potential," cited by 15% of doctors as an advantage. It is believed that "low abuse potential" was among the deceptive messages that New York State and City of Syracuse prescribers received, and retained, from ENDO sales representatives.

757. ENDO's own internal documents, however, acknowledged the misleading nature of these statements, conceding that "Opana ER has an abuse liability similar to other opioid analgesics as stated in the [FDA-mandated] box warning." A September 2012 Opana ER Business Plan similarly stated that ENDO needed a significant investment in clinical data - to support comparative effectiveness, scientific exchange, benefits and unmet need, while citing lack of "head-to-head data" as a barrier to greater share acquisition.

758. Nevertheless, ENDO knew its marketing was extremely effective in turning physicians into prescribers. Nationally, the physicians they targeted for in-person marketing represented approximately 84% of all prescriptions for Opana ER in the first quarter of 2010. ENDO also observed the prescribers that its sales representatives visited wrote nearly three times as many prescriptions per month for Opana ER as those physicians who weren't targeted for ENDO's marketing, which equated to 7.4 prescriptions per month versus 2.5. The most heavily targeted prescribers wrote nearly 30 prescriptions per month. Internal documents from May 2008 indicate that ENDO expected that each of its sales representatives would generate 19.6 prescriptions per week by the end of 2008. As summarized by a February 2011 report on Opana ER growth trends, ENDO's "[a]ggressive detailing [is] having an impact."

759. More broadly, ENDO's sales trainings and marketing plans demonstrate that its sales force was trained to provide prescribers with misleading information regarding the risks of opioids when used to treat chronic pain. Foremost among these messages, were misleading

claims that the risks of addiction, diversion, and abuse associated with opioids - and ENDO's products in particular - were low, and lower than other opioids.

i. ENDO's Sales Force Deceptively Minimized the Risks of Addiction Associated with Chronic Opioid Therapy

760. By way of illustration, ENDO's Opana ER INTAC Technology Extended-Release Sell Sheet Implementation Guide, which instructs ENDO sales personnel how to effectively "support key messages" related to the marketing of Opana ER, states that it is an "approved message" for sales representatives to stress that Opana ER was "designed to be crush resistant," even though this internal document conceded that "the clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER."

761. Other ENDO documents acknowledged the limitations on Opana ER's INTAC technology, conceding that while Opana ER may be resistant to pulverization, it can still be "ground" and "cut into small pieces" by those looking to abuse the drug.

762. ENDO's claims about the crush-resistant design of Opana ER also made their way to the company's press releases. A January 2013 article in *Pain Medicine News*, based in part on an ENDO press release, described Opana ER as "crush-resistant." This article was posted on the *Pain Medicine News* website, which was accessible to New York State and City of Syracuse patients and prescribers.

763. ENDO could only have promoted the crush resistance of Opana ER in order to persuade doctors that there was less risk of abuse, misuse, and diversion of the drug. The claim that ENDO's drugs are less addictive than other drugs was the precise message, upon information and belief, that New York State and City of Syracuse prescribers took from ENDO's marketing.

764. Accordingly, on May 10, 2013, the FDA warned ENDO that there was no evidence that Opana ER's design "would provide a reduction in oral, intranasal, or intravenous

abuse” and that the post-marketing data ENDO had submitted to the FDA “are insufficient to support any conclusion about the overall or route-specific rates of abuse.” Even though it was rebuked by the FDA, ENDO continued to market Opana ER as having been designed to be crush resistant, knowing that this would (falsely) imply that Opana actually *was* crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused.

765. ENDO's sales training and the promotional materials distributed by its sales representatives also minimized the risk of addiction. For example, ENDO circulated an education pamphlet with the ENDO logo titled *Living with Someone with Chronic Pain*, which implied to persons providing care to chronic pain patients that addiction was not a substantial concern by stating that “[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem.” This program was downloadable from ENDO's website and accessible to New York State and City of Syracuse prescribers.

766. ENDO's sales training also misrepresented the risks of addiction associated with ENDO's products by implying that ENDO's prolonged absorption would make it less likely to lead to abuse. For example, a presentation titled “*Deliver the Difference for the Opana Brand in POA II*” sets out that one of the “[k]ey [m]essages” for the ENDO sales force was that Opana ER provides “[s]table, steady-state plasma levels for true 12-hour dosing that lasts.” As outlined below, ENDO's sales representatives used this messaging to imply to New York State and City of Syracuse prescribers that Opana ER provided “steady state” pain relief, making Opana less likely to incite euphoria in patients and less likely to lead to addiction.

767. ENDO further instructed its sales force to promote the misleading concept of “pseudoaddiction,” (*i.e.*, that drug-seeking behavior was not cause for alarm, but merely a manifestation of undertreated pain). In a sales training document titled “*Understanding the*

Primary Care MD and the use of Opioids,” ENDO noted that the “biggest concerns” among primary care physicians were “prescription drug abuse (84.2%), addiction (74.9%), adverse effects (68%), tolerance (60.7%), and medication interaction (32%).” In response to these concerns, ENDO instructed its sales representatives to ask whether their customers are “confus[ing] ‘pseudo-addiction’ with ‘drug-seekers’” and how confident they are that their health care providers “know these differences (Tolerance, Dependence, Addiction, Pseudo-Addiction...).”

ii. ENDO’s Sales Force Deceptively Implied that Chronic Opioid Therapy Would Improve Patient’s Ability to Function.

768. In addition to their deceptive messages regarding addiction, ENDO’s promotional materials and sales trainings also misleadingly claimed that patients using opioids for the long-term treatment of chronic pain would experience improvements in their daily function. In reality, long-term opioid use has not been shown to and does not improve patients’ function, and, in fact, often is accompanied by serious side effects that degrade function. ENDO’s own internal documents acknowledged that claims about improved quality of life were unsubstantiated “off label claims.”

769. Nevertheless, ENDO distributed product advertisements that suggested that using Opana ER to treat chronic pain would allow patients to perform demanding tasks like work as a chef. One such advertisement states prominently on the front: “Janice is a 46-year-old chef with chronic low back pain. She needs a treatment option with true 12-hour dosing.” The advertisement does not mention the “moderate to severe pain” qualification in Opana ER’s indication, except in the fine print. These advertisements were mailed to prescribers and distributed by ENDO’s sales force in detailing visits, which would have included ENDO

representatives' visits to New York State and City of Syracuse prescribers.

770. In a 2007 Sales Tool that was intended to be shown by ENDO sales personnel to physicians during their detailing visits, ENDO highlighted a hypothetical patient named Bill, who was a 40-year-old construction worker that suffered from chronic low back pain. According to the Sales Tool, Opana ER "will make it more likely that Bill can return to work and support his family."

771. Similarly, training materials for sales representatives from March 2009, ask whether it is true or false that "[t]he side effects of opioids prevent a person from functioning and can cause more suffering than the pain itself." The materials indicate that this is "[f]alse" because "[t]he overall effect of treatment with opioids is very favorable in most cases."

772. A sales training video dated March 8, 2012, that ENDO produced and used to train its sales force, makes the same types of claims. A patient named Jeffery explains in the video that he suffers from chronic pain and that "chronic pain [...] reduces your functional level." Jeffery claims that after taking Opana ER, he "can go out and do things" like attend his son's basketball game and "[t]here's no substitute for that." This video was shown to ENDO's sales force, which adopted its misleading messaging in its nationwide sales approach, including the approach it used in New York and in the City of Syracuse.

773. Claims of improved functionality were central to ENDO's marketing efforts for years. A 2012 ENDO Business Plan lists ways to position Opana ER, and among them is the claim that Opana ER will help patients "[m]aintain normal functionality, sleep, [and] work/life/performance productivity" and have a positive "[e]ffect on social relationships." Indeed, that business plan describes the "Opana ER Vision" as "[t]o make the Opana franchise (Opana ER, Opana, Opana Injection) the choice that maximizes improvement in functionality

and freedom from the burden of moderate-to-severe pain.”

iii. Endo’s Sales Force Deceptively Presented the Risks and Benefits of Opioids To Make Them Appear Safer Than Other Analgesics

774. ENDO further misled patients and prescribers by downplaying the risks of opioids in comparison to other pain relievers. For example, it distributed in New York State and in the City of Syracuse and elsewhere a presentation titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. This study held out, as a representative example, one patient who had taken NSAIDs for more than eight years and, as a result, developed “a massive upper gastrointestinal bleed.” The presentation recommended treating this patient with opioids instead. By focusing on the adverse side effects of NSAIDs, while omitting discussion of serious side effects associated with opioids, this presentation misleadingly portrayed the comparative risks and benefits of these drugs.

775. ENDO distributed *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* to 116,000 prescribers in 2007, including primary care physicians.

b. ENDO’s Speakers’ Bureau Programs Deceptively Minimized the Risks of Addiction Associated with Chronic Opioid Therapy

776. In addition to its sales representatives’ visits to doctors, ENDO also used deceptive science and speaker programs to spread its deceptive messages.

777. ENDO leaned heavily on its speakers’ bureau programs. In 2008 alone, ENDO spent nearly \$4 million to promote up to 1,000 speakers’ programs around the country. ENDO contracted with a medical communications firm to operate its speakers’ bureau program, planning to hold a total of 500 “fee-for-service ... peer-to-peer promotional programs” for Opana ER in just the second half of 2011, including dinners, lunches and breakfasts. These programs were attended by sales representatives, which reveal their true purpose as marketing, rather than

educational, events.

778. ENDO's internal reporting stated that the "return on investment" turned positive 8-12 weeks after such programs. ENDO measured that return on investment in numbers of prescriptions written by physicians who attended the events. One internal ENDO document concluded: "[w]e looked at the data for [the] 2011 program and the results were absolutely clear: physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than they had before they participated. You can't argue with results like that."

779. These speakers' bureau presentations included the very same misrepresentations ENDO disseminated through its sales representatives. A 2012 speaker slide deck for Opana ER - on which ENDO's recruited speakers were trained and to which they were required to adhere to in their presentations - misrepresented that the drug had low abuse potential, in addition to suggesting that as many as one-quarter of the adult population could be candidates for opioid therapy.

780. In addition, a 2013 training module directed speakers to instruct prescribers that "OPANA ER with INTAC is the only oxymorphone designed to be crush resistant" and advise that "[t]he only way for your patients to receive oxymorphone ER in a formulation designed to be crush resistant is to prescribe OPANA ER with INTAC." This was a key point in distinguishing Opana ER from competitor drugs. Although ENDO mentioned that generic versions of oxymorphone were available, it instructed speakers to stress that "[t]he generics are not designed to be crush resistant." This was particularly deceptive given that Opana ER was not actually crush resistant.

781. In 2009, ENDO wrote a talk titled *The Role of Opana ER in the Management of Chronic Pain*. The talk included a slide titled "Use of Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain," which cited the AAPM/APS Guidelines - and, as described above,

their accompanying misstatements regarding the likelihood of addiction (by claiming that addiction risks were manageable regardless of patients' past abuse histories) while omitting their disclaimer regarding the lack of supporting evidence in favor of that position. This dangerously misrepresented to doctors the force and utility of the 2009 Guidelines.

782. The misleading messages and materials ENDO provided to its sales force and its speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included New York State and City of Syracuse as described above, ENDO's nationwide messages would have reached New York State and City of Syracuse prescribers in a number of ways. For example, they were carried into New York State and City of Syracuse by ENDO's sales representatives during detailing visits as well as made available to New York and Onondaga County patients and prescribers through websites and ads. They also have been delivered to New York State and City of Syracuse prescribers by ENDO's paid speakers, who were required by ENDO policy and by FDA regulations to stay true to ENDO's nationwide messaging.

c. ENDO's Misleading Journal Supplement

783. In 2007, ENDO paid to have published a supplement available for CME credit in the *Journal of Family Practice* called *Pain Management Dilemmas in Primary Care: Use of Opioids*, and it deceptively minimized the risk of addiction by emphasizing the effectiveness of screening tools. Specifically, it recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain. It also falsely claimed that, through the use of tools like toxicology screens, pill counts, and a "maximally structured approach," even patients at high risk of addiction could safely receive chronic opioid therapy. ENDO distributed 96,000 copies of this CME nationwide, and it was available to and was

intended to reach New York and City of Syracuse prescribers.

d. ENDO's Deceptive Unbranded Advertising

784. ENDO also used unbranded advertisements to advance its goals. By electing to focus on unbranded marketing, ENDO was able to make claims about the benefits of its opioids that the FDA would never allow in its branded materials. The chart below compares an ENDO unbranded statement with one of ENDO's FDA-regulated, branded statements:

Living with Someone with Chronic Pain (2009) (Unbranded)	Opana ER Advertisement (2011/2012/2013) (Branded)
Patient education material created by ENDO	ENDO advertisement
“Most health care providers who treat people pain agree that most people do not develop an addiction problem.”	<p>“[C]ontains oxymorphone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit”</p> <p>“All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use.”</p>

2. Endo's Deceptive Third-Party Statements

785. ENDO's efforts were not limited directly to making misrepresentations through its marketing materials, its speakers and its sales force. ENDO believed that support for patient advocacy and professional organizations would reinforce ENDO's position as “the pain management company.”

786. Prior to, but in contemplation of, the 2006 launch of Opana ER, ENDO developed a “Public Stakeholder Strategy.” ENDO identified “tier one” advocates to assist in

promoting the approval and acceptance of its new extended release opioid. ENDO also intended to enlist the support of organizations that engage or have the potential to advocate for public policy that would be “favorable” to Schedule II opioids from a sales perspective. ENDO sought to develop its relationships with these organizations through its funding. In 2008, ENDO spent \$1 million per year to attend conventions of these pro-opioid medical societies, including meetings of AAPM, APS, and the American Society of Pain Management Nursing (“ASPMN”).

787. APF's ability to influence professional societies and other third parties is demonstrated by its approach in responding to a citizens' petition filed with the FDA by the Physicians for Responsible Opioid Prescribing (the “PROP Petition”). The PROP petition, filed by a group of prescribers who had become concerned with the rampant prescribing of opioids to treat chronic pain, asked the FDA to require dose and duration limitations on opioid use and to change the wording of the approved indication of various long-acting opioids to focus on the severity of the pain they are intended to treat.

788. The PROP Petition set off a flurry of activity at ENDO. It was a given that ENDO would respond to the petition. The only question among ENDO personnel was “[s]hould we [...] consider filing a direct response to this [citizens' petition] or do you think we are better served by working through our professional society affiliations?” One ENDO employee responded: “My sense is the societies are better placed to make a medical case than ENDO.” ENDO's Director of Medical Science agreed that “a reply from an external source would be most impactful.” These communications reflected ENDO's absolute confidence that the professional societies would support its position.

a. APF

789. APF was one of the societies with which ENDO worked most closely. ENDO

provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its NIPC. ENDO was one of APF's biggest financial supporters, and ENDO provided more than half of the \$10 million APF received from opioid manufacturers during its lifespan. ENDO spent \$1.1 million on the NIPC program in 2008 alone, funding earmarked, in part, for the creation of CME materials that were intended to be used over and over again.

790. ENDO's influence over APF's activities was so pervasive that APF's President Will Rowe even reached out to Defendants - including ENDO - rather than his own staff to identify potential authors to answer an article critical of opioids that appeared in the *Archives of Internal Medicine* in 2011. Personnel from Defendants PURDUE, ENDO, JANSSEN, and CEPHALON worked with Rowe to formulate APF's response. The response suggested by Defendants was the one that APF ultimately published.

791. Documents also indicate that ENDO personnel were given advance notice of materials APF planned to publish on its website and provided an opportunity to comment on the content of those materials before they were published. For example, in early July of 2009, APF's Director of Strategic Development wrote to ENDO personnel to give them advance notice of content that APF planned to be "putting ... up on the website but it's not up yet." This ENDO employee also reassured the sender that she "will not forward it to anyone at all" and promised that she would "double delete it from [her] inbox." In response, APF's Director of Strategic Development replied internally with only four words: "And where's the money?"

792. Nowhere was ENDO's relationship with APF closer than with its sponsorship of the NIPC. Before being taken over by APF, the NIPC was sponsored by Professional Postgraduate Services, but that company was determined to be a "commercial interest" by the

ACCME and could no longer serve as a sponsor. In response, ENDO reached out to APF. An August 2009 document titled, *A Proposal for the American Pain Foundation to Assume Sponsorship of the National Initiative on Pain Control*, pointed out that “[f]or the past 9 years, the NIPC has been supported by unrestricted annual grants from ENDO Pharmaceuticals, Inc.” According to this document, APF’s sponsorship of the NIPC “[o]ffers the APF a likely opportunity to generate new revenue, as ENDO has earmarked substantial funding: \$1.2 million in net revenue for 2010 to continue the NIPC.” Further, sponsorship of the APF would “[p]rovide[] numerous synergies to disseminate patient education materials,” including ... [h]andouts to attendees at all live events to encourage physicians to drive their patients to a trusted source for pain education—the APF website.”

793. A September 14, 2009 presentation to APF’s board contained a materially similar discussion of NIPC sponsorship, emphasizing the financial benefit to APF from assuming the role of administering NIPC. The proposal “offer[ed] a solution to continue the development and implementation of the NIPC initiative as non-certified...yet independent education to physicians and healthcare professionals in the primary care setting, while providing the APF with a dependable, ongoing source of grant revenue.” A number of benefits related to NIPC sponsorship were listed, but chief among them was “a likely opportunity [for APF] to generate new revenue, as ENDO has earmarked substantial funding: \$1.2 million in net revenue for 2010 to continue the NIPC.”

794. Internal ENDO scheduling documents indicate that “NIPC module curriculum development, web posting, and live regional interactive workshops” were ENDO promotional tasks in 2010. ENDO emails indicate that ENDO personnel reviewed the content created by NIPC and provided feedback.

795. Behind the scenes, ENDO exercised substantial control over NIPC’s work.

ENDO exerted its control over NIPC by funding NIPC and APF projects; developing, specifying, and reviewing content; and taking a substantial role in distribution of NIPC and APF materials, which in effect determined which messages were actually delivered to prescribers and consumers. As described below, ENDO projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

796. From 2007 until at least 2011, ENDO also meticulously tracked the distribution of NIPC materials, demonstrating ENDO's commercial interest in and access to NIPC's reach. ENDO knew exactly how many participants viewed NIPC webinars and workshops and visited its website, *Painknowledge.com*. ENDO not only knew how many people viewed NIPC's content, but what their backgrounds were (*e.g.* primary care physicians or neurologists). ENDO's access to and detailed understanding of the composition of the audience at these events demonstrates how deeply ENDO was involved in NIPC's activities. Moreover, ENDO tracked the activities of NIPC - ostensibly a third party - just as it tracked its own commercial activity.

797. ENDO worked diligently to ensure that the NIPC materials it helped to develop would have the broadest possible distribution. ENDO's 2008 to 2012 Opana Brand Tactical Plan indicates that it sought to reach 1,000 prescribers in 2008 through live NIPC events, and also to "[l]everage live programs via enduring materials and web posting." ENDO also planned to disseminate NIPC's work by distributing two accredited newsletters to 60,000 doctors nationwide for continuing education credit and sponsoring a series of 18 NIPC regional case-based interactive workshops. ENDO had earmarked more than one million dollars for NIPC activities in 2008 alone.

798. In short, NIPC was a key piece of ENDO's marketing strategy. Indeed, internal APF emails question whether it was worthwhile for APF to continue operating NIPC given that the NIPC's work was producing far more financial benefit for ENDO than for APF. Specifically,

after ENDO approved a \$244,337.40 grant request to APF to fund a series of NIPC eNewsletters, APF personnel viewed it as “[g]reat news,” but cautioned that “the more I think about this whole thing, [ENDO's] making a lot of money on this with still pretty slender margins on [APF's] end.” APF's commitment to NIPC's “educational” mission did not figure at all in APF's consideration of the value of its work, nor was ENDO's motive or benefit in doubt.

i. Misleading Medical Education

799. NIPC distributed a series of eNewsletter CMEs focused on “key topic[s] surrounding the use of opioid therapy” and sponsored by ENDO. These newsletters were edited by KOL Dr. Perry Fine and also listed several industry-backed KOLs, including Dr. Lynn Webster, as individual authors. ENDO estimated that roughly 60,000 prescribers viewed each one, which were available to and would have included New York State and City of Syracuse prescribers. Before-and-after surveys, summarized in the chart below, showed that prescriber comfort with prescribing opioids ranged from 27% to 62% before exposure to the CME, and from 76% to 92% afterwards:

Topic:	Comfort level <u>prior to</u> reading the article	Comfort level <u>after</u> reading the article
Patient Selection and Initiation of Opioid Therapy as a Component of Pain Treatment	47%	87%
Informed Consent and Management Plans to Optimized Opioid Therapy for Chronic Pain	48%	81%
Risk Stratification and Evaluation of High-Risk Behaviors for Chronic Opioid Therapy	28%	76%
Integration of Nonpharmacologic and Multidisciplinary Therapies into the Opioid Treatment Plan	42%	85%

Addressing Patients' Concerns Associated with Chronic Pain and Opioid Use	62%	92%
Opioid Therapy in Patients with a History of Substance Use Disorders	35%	85%
Urine Drug Testing: An Underused Tool	54%	86%
Appropriate Documentation of Opioid Therapy: The Emergence of the 4As and Trust and Verify as the Paradigm	44%	86%
Opioid Rotation	27%	92%
Discontinuing Opioid Therapy: Developing and Implementing an "Exit Strategy"	37%	90%

800. ENDO documents made clear that the persuasive power of NIPC speakers was directly proportional to their perceived objectivity. Accordingly, ENDO personnel directed that, when giving ENDO-sponsored talks, NIPC faculty would not appear to be "ENDO Speakers." Nevertheless, the two parties understood that ENDO and NIPC shared a common "mission to educate physicians" and working "through the APF ... [w]as a great way to work out ... problems that could have been there without the APF's participation and support."

801. The materials made available on and through NIPC included misrepresentations. For example, ENDO worked with NIPC to sponsor a series of CMEs titled *Persistent Pain in the Older Patient* and *Persistent Pain in the Older Adult*. These CMEs misrepresented the prevalence of addiction by stating that opioids have "possibly less potential for abuse" in elderly patients than in younger patients, even though there is no evidence to support such an assertion. Moreover, whereas withdrawal symptoms are always a factor in discontinuing long-term opioid therapy, *Persistent Pain in the Older Adult* also misleadingly indicated that such symptoms can be avoided entirely by tapering the patient's doses by 10-20% per day for ten days. *Persistent Pain in the Older Patient*, for its part, made misleading claims that opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." NIPC webcast these CMEs from its own website, where they

were available to and were intended to reach New York State and City of Syracuse prescribers.

ii. *Painknowledge.com*

802. Working with NIPC enabled ENDO to make a number of misleading statements through the NIPC's website, *Painknowledge.com*. ENDO tracked visitors to *PainKnowledge.com* and used this website to broadcast notifications about additional NIPC programming that ENDO helped to create.

803. APF made a grant request to ENDO to create an online opioid “tool-kit” for NIPC and to promote NIPC's website, *Painknowledge.com*. In so doing, APF made clear that it planned to disseminate Defendants' misleading messaging. The grant request expressly indicated APF's intent to make misleading claims about functionality, noting: “some of these people [in chronic pain] may be potential candidates for opioid analgesics, which can improve pain, function, and quality of life.” ENDO provided \$747,517 to fund the project.

804. True to APF's word, *Painknowledge.com* misrepresented that opioid therapy for chronic pain would lead to improvements in patients' ability to function. Specifically, in 2009 the website instructed patients and prescribers that, with opioids, a patient's “level of function should improve” and that patients “may find [they] are now able to participate in activities of daily living, such as work and hobbies, that [they] were not able to enjoy when [their] pain was worse.”

805. *Painknowledge.com* also deceptively minimized the risk of addiction by claiming that “[p]eople who take opioids as prescribed usually do not become addicted.” *Painknowledge.com* did not stop there. It deceptively portrayed opioids as safe at high doses and also misleadingly omitted serious risks, including the risks of addiction and death, from its description of the risks associated with the use of opioids to treat chronic pain.

806. ENDO was the sole funder of *Painknowledge.com*, and it continued to provide that funding despite being aware of the website's misleading contents.

iii. *Exit Wounds*

807. Finally, ENDO also sponsored APF's publication and distribution of *Exit Wounds*, a publication aimed at veterans that also contained a number of misleading statements about the risks, benefits, and superiority of opioids to treat chronic pain. *Exit Wounds* was drafted by "Medical Writer X," whose extensive work for JANSSEN is described below. Medical Writer X was frequently hired by a Consulting Firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Medical Writer X's work was reviewed and approved by drug company representatives, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.

808. *Exit Wounds* is a textbook example of Medical Writer X's authorship on drug companies' behalf. The book misrepresented the functional benefits of opioids by stating that opioid medications "*increase your level of functioning*" (emphasis in original).

809. *Exit Wounds* also misrepresented that the risk of addiction associated with the use of opioids to treat chronic pain was low. It claimed that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."

810. Finally, *Exit Wounds* misrepresented the safety profile of using opioids to treat chronic pain by omitting key risks associated with their use. Specifically, it omitted warnings of the risk of interactions between opioids and benzodiazepines - a warning sufficiently important to be included on ENDO's FDA-required labels. *Exit Wounds* also contained a lengthy discussion of the

dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids - a particular risk for veterans.

811. As outlined above, ENDO exercised dominance over APF and the projects it undertook in an effort to promote the use of opioids to treat chronic pain. In addition, as outlined above, Medical Writer X's work was being reviewed and approved by drug company representatives, motivating him to draft pro-opioid propaganda masquerading as science. Combined, these factors gave ENDO considerable influence over the work of Medical Writer X and over APF. Further, by paying to distribute *Exit Wounds*, ENDO endorsed and approved its contents.

b. Other Front Groups: FSMB, AAPM, and AGS

812. In addition to its involvement with APF, ENDO worked closely with other third-party Front Groups and KOLs to disseminate deceptive messages regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. As with certain APF publications, ENDO in some instances used its sales force to directly distribute certain publications by these Front Groups and KOLs, making those publications "labeling" within the meaning of 21 C.F.R. §1.3(a).

813. In 2007, ENDO sponsored FSMB's *Responsible Opioid Prescribing*, which, as described above, in various ways deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* was drafted by "Medical Writer X."

814. ENDO spent \$246,620 to help FSMB distribute *Responsible Opioid Prescribing*. ENDO approved this book for distribution by its sales force. Based on the uniform and nationwide character of ENDO's marketing campaign, and the fact that ENDO purchased these copies specifically to distribute them, these copies were distributed to physicians nationwide, including physicians in New York State and City of Syracuse.

815. In December 2009, ENDO also contracted with AGS to create a CME to

promote the 2009 guidelines titled the *Pharmacological Management of Persistent Pain in Older Persons* with a \$44,850 donation. As described above, these guidelines misleadingly claimed that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse,” since the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that “[a]ll patients with moderate to severe pain ... should be considered for opioid therapy (low quality of evidence, strong recommendation)” when in reality, opioid therapy was an appropriate treatment only for a subset of those patients, as ENDO’s FDA-mandated labels recognized.

816. AGS's grant request to ENDO made explicit reference to the CME that ENDO was funding. ENDO thus knew full well what content it was paying to distribute, and was in a position to evaluate that content to ensure it was accurate, substantiated, and balanced before deciding whether to invest in it. After having sponsored it, ENDO’s internal documents indicate that ENDO’s pharmaceutical sales representatives discussed the AGS guidelines with doctors during individual sales visits.

817. ENDO also worked with AAPM, which it viewed internally as “Industry Friendly,” with ENDO advisors and speakers among its active members. ENDO attended AAPM conferences, funded its CMEs, and distributed its publications.

818. A talk written by ENDO in 2009, approved by ENDO's Medical Affairs Review Committee,¹⁶⁸ titled *The Role of Opana ER in the Management of Chronic Pain*,

¹⁶⁸ Although given slightly different names by each Defendant, each Defendant employed a committee that would review and approve materials for distribution. These committees included representatives from all relevant departments within their organizations, including the legal, compliance, medical affairs, and marketing departments. The task of these review committees was to scrutinize the marketing materials Defendants planned to distribute and to ensure that those materials were scientifically accurate and legally sound. Tellingly, these committees were called to review only materials that created a potential compliance issue for the company, an implicit recognition by Defendants that they ultimately would be responsible for the content under review.

includes a slide titled *Use of Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain*. That slide cites the AAPM/APS Guidelines, which contain a number of misstatements as outlined above, while omitting their disclaimer regarding the lack of supporting evidence. This dangerously misrepresented to doctors the force and utility of the 2009 Guidelines. Furthermore, ENDO's internal documents indicate that pharmaceutical sales representatives employed by ENDO, ACTAVIS, and PURDUE discussed treatment guidelines with doctors during individual sales visits.

c. Key Opinion Leaders and Misleading Science

819. ENDO also sought to promote opioids for the treatment of chronic pain through the use of key opinion leaders and biased, misleading science.

820. ENDO's 2010 publication plan for Opana ER identified a corporate goal of making Opana ER the second-leading branded product for the treatment of moderate-to-severe chronic pain (after OxyContin). ENDO sought to achieve that goal by providing "clinical evidence for the use of Opana ER in chronic low back pain and osteoarthritis," and succeeded in having articles on this topic published.¹⁶⁹

821. In the years that followed, ENDO sponsored articles, authored by an ENDO consultant and ENDO employees, which argued that the metabolic pathways utilized by Opana ER made it less likely than other opioids to result in drug interactions in elderly low back and osteoarthritis pain patients. In 2010, ENDO directed its publication manager to reach out to a list of consultants conducting an ongoing ENDO-funded study, to assess their willingness to respond to an

¹⁶⁹ *These studies suffered from the limitations common to the opioid literature—and worse. None of the comparison trials lasted longer than three weeks. ENDO also commissioned a six-month, open label trial during which a full quarter of the patients failed to find a stable dose, and 17% of patients discontinued, citing intolerable effects. In open label trials, subjects know which drug they are taking; such trials are not as rigorous as double-blind, controlled studies in which neither the patients nor the examiners know which drugs the patients are taking.*

article¹⁷⁰ that ENDO believed emphasized the risk of death from opioids, “without fair balance.”¹⁷¹

822. ENDO’s reliance on flawed, biased research is also evident in its 2012 marketing materials and strategic plans. A 2012 Opana ER slide deck for ENDO’s speakers’ bureaus - on which these recruited physician speakers were trained and to which they were required to adhere - misrepresented that the drug had low abuse potential and suggested that as many as one-quarter of the adult population could be candidates for opioid therapy. Although the FDA requires such speaker slide decks to reflect a “fair balance” of information on benefits and risks, ENDO’s slides reflected one-sided and deeply biased information. The presentation’s 28 literature citations were largely to “data on file” with the company, posters, and research funded by or otherwise connected to ENDO. ENDO’s speakers carried the information in these slides to audiences that were unaware of the skewed science on which the information rested.

823. A 2012 Opana ER Strategic Platform Review suffered from similar defects. Only a small number of the endnote references in that document, which it cites to indicate “no gap” in scientific evidence for particular claims, were to national-level journals. Many were published in lesser or dated journals, and written or directly financially supported by opioid manufacturers. Where the strategy document did cite independent, peer-reviewed research, it did so out of context. For example, it cited a 2008 review article of opioid efficacy for several claims, including that “treatment of chronic pain reduces pain and improves functionality,” but it ignores that article’s overall focus on “the lack of consistent effectiveness of opioids in reducing pain and improving functional status.”¹⁷²

170 Susan Okie, *A Flood of Opioids, a Rising Tide of Deaths*, 363 *New Engl. J. Med.* 1981 (2010), finding that opioid overdose deaths and opioid prescriptions both increased by roughly 10-fold from 1990 to 2007.

171 ENDO did manage to get a letter written by three of those researchers, which was not published.

172 Andrea M. Trescot et al., *Opioids in the management of non-cancer pain: an update of American Society of the Interventional Pain Physicians. Pain Physician 2008 Opioid Special Issue, S5-S2.*

824. Notwithstanding ENDO's reliance upon dubious or cherry-picked science, in an Opana ER brand strategy plan it internally acknowledged the continuing need for a significant investment in clinical data to support comparative effectiveness. ENDO also cited a lack of "head-to-head data" as a barrier to greater share acquisition and the "lack of differentiation data" as a challenge to addressing the "#1 Key Issue" of product differentiation. Nor did this acknowledged lack of support stop ENDO from directing its sales representatives to tell prescribers that its drugs were less likely to be abused or less addictive than other opioids.

825. ENDO also worked with various KOLs to disseminate various misleading statements about chronic opioid therapy. For example, ENDO distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding your Pain: Taking Oral Opioid Analgesics*. This pamphlet deceptively minimized the risks of addiction by stating that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems," implying that patients who are taking opioids for pain are not at risk of addiction.

826. *Understanding your Pain: Taking Oral Opioid Analgesics* also misleadingly omitted any description of the increased risks posed by higher doses of opioid medication. Instead, in a Q&A format, the pamphlet asked "[i]f I take the opioid now, will it work later when I really need it?" and responded that "[t]he dose can be increased... [y]ou won't 'run out' of pain relief."

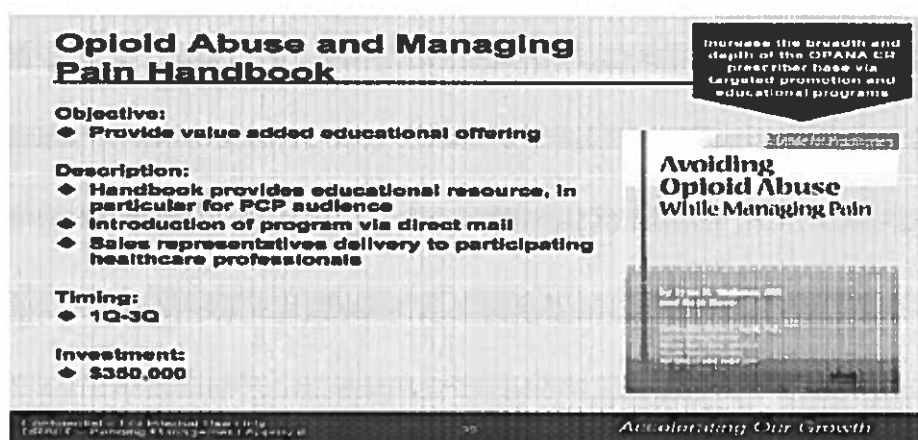
827. Dr. Russell Portenoy received research support, consulting fees, and honoraria from ENDO forediting *Understanding Your Pain* and other projects.

828. *Understanding Your Pain* was available on ENDO's website during the time period of this Complaint and was intended to reach New York State and City of Syracuse prescribers.

829. ENDO similarly distributed a book written by Dr. Lynn Webster, titled

Avoiding Opioid Abuse While Managing Pain, which stated that in the face of signs of aberrant behavior, increasing the dose “in most cases ... should be the clinician's first response.”

830. A slide from an Opana ER business plan contemplated distribution of the book as part of ENDO's efforts to “[i]ncrease the breadth and depth of the OPANA ER prescriber base via targeted promotion and educational programs.” The slide indicates that the book would be particularly effective “for [the] PCP audience” and instructed “[s]ales representatives [to] deliver [the book] to participating health care professionals.” The slide, shown below, demonstrates ENDO's express incorporation of this book by a KOL into its marketing strategy:



831. ENDO documents indicate that, around 2007, the company purchased at least 50,000 copies of the book for distribution. Internal ENDO documents demonstrate that the book had been approved for distribution by ENDO's sales force, and ENDO had fewer than 8,000 copies on hand in March of 2013. Based on the nationwide and uniform character of ENDO's marketing, and the book's approval for distribution, this book was available to and was intended to reach New York State and City of Syracuse prescribers.

3. ENDO's Deceptive Statements to New York and City of Syracuse Prescribers and Patients

832. ENDO also directed the dissemination of the misstatements described above to

New York State and City of Syracuse patients and prescribers, including through its sales force, speakers' bureaus, CMEs, and the *Painknowledge.com* website.

833. Consistent with their training, ENDO's sales representatives delivered all of these deceptive messages to New York State and City of Syracuse prescribers. ENDO's sales representatives marketed principally to internists. ENDO's sales representatives weren't taught about the risks of long-term opioid use while working at ENDO and the risks were not a focus of their training. It has been reported by former ENDO's sales representatives that they were familiar with the term "pseudoaddiction", however, they would dodge any questions about addiction, telling doctors that they lacked the documentation or data to talk about it.

834. ENDO specifically targeted physicians who prescribed Vicodin and NSAIDs. ENDO's sales representatives were trained to persuade these physicians to prescribe ENDO's drugs by discussing milder side effects associated with the drugs, like constipation and itching skin. ENDO's sales representatives frequently told doctors that prescribing Opana ER to their patients would improve patients' ability to function. Finally, ENDO's sales representatives left copies of *Understanding Your Pain: Taking Oral Opioid Analgesics* with the prescribers they detailed. As described above, this publication misleadingly implied that pain patients prescribed opioids would not become addicted.

835. ENDO's national marketing campaign included the misrepresentations described above, and that the company disseminated these same misrepresentations to New York State and City of Syracuse prescribers and consumers. In particular, ENDO's sales representatives omitted or minimized the risk of opioid addiction; claimed that ENDO's drugs would be less problematic for patients because they were tamper resistant and "steady state" and claimed or implied that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by

making claims of improved function.

836. ENDO promoted Opana ER as less addictive than other opioids with “minimal” abuse potential, or a “lower” abuse potential, presumably as compared to other opioids. Further, beginning in 2012, ENDO sales representatives promoted the “Intac” formulation as being affirmatively crush resistant, despite FDA findings to the contrary. For example, ENDO representatives told pain specialists that Opana ER was “tamper proof” or “difficult to abuse.” ENDO sales representatives also claimed that the fact that Opana ER was a long-acting formulation made it less addicting, despite its Schedule II classification. Finally, Opana ER sales representatives that the sustained release had the properties of “hopefully avoiding addiction”.

837. ENDO also entered into speaking engagements with prescribers, which demonstrate the complete control that ENDO exerted over the content of their presentations. ENDO required that their speakers/prescribers “will attend and participate in those speaker programs requested by ENDO” and that “ENDO will select the topics for all presentations which will be based upon slides, outlines or materials provided and approved by ENDO.” Further, “[a]ll materials provided by ENDO must be presented in their entirety or without alterations.”

838. Moreover, these paid speaking engagements incentivized these prescribers to write prescriptions for ENDO's opioids, because only doctors who wrote ENDO prescriptions were considered for these roles.

839. ENDO also directed misleading marketing to New York State and City of Syracuse prescribers and patients through the APF/NIPC materials it sponsored, reviewed, and approved. For example, ENDO hired KOLs to deliver the CME *Managing Persistent Pain in the Older Patient*, which CME misrepresented the prevalence of addiction in older patients and made misleading claims that chronic opioid therapy would improve patients’ ability to function. Email

invitations to NIPC programs were sent to “all healthcare professionals” in APF’s database.

840. Another CME, *Persistent Pain in the Older Adult*, was presented by KOLs hired by ENDO, which CME also trivialized the risks associated with opioid withdrawal by stating that withdrawal symptoms can be eliminated entirely.

841. The significant response to *Painknowledge.com* also indicates that those websites were viewed by New York State and City of Syracuse area prescribers, who were exposed to the site’s misleading information regarding the effect of opioids on patients’ ability to function and the deceptive portrayal of the risk of opioids. As of September 14, 2011, *Painknowledge.com* had 10,426 registrants, 86,881 visits, 60,010 visitors, and 364,241 page views. Upon information and belief, based on the site’s nationwide availability, among the site’s visitors were New York State and City of Syracuse patients and prescribers who were exposed to the site’s misleading information regarding the effect of opioids on patients’ ability to function and the deceptive portrayal of the risks of opioids.

842. ENDO knew that the harms for its deceptive marketing would be felt in New York State and City of Syracuse. It saw workers’ compensation programs as a lucrative opportunity, and it promoted the use of opioids for chronic pain arising from work-related injuries, like chronic lower back pain. ENDO developed plans to “drive demand for access through the employer audience by highlighting cost of disease and productivity loss in those with pain; [with a] specific focus on high-risk employers and employees.” In 2007, ENDO planned to reach 5,000 workers’ compensation carriers in order to ensure that Opana ER would be covered under disability insurance plans, and, as such, many claims for opioids have been paid by municipal worker’s compensation programs.

843. ENDO has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with ENDO, the State of New York found that ENDO failed to require sales representatives to report signs of abuse, diversion,

and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

F. MALLINCKRODT

844. As described herein, MALLINCKRODT marketed and promoted its drugs, including generic oxycodone, of which it is one of the largest manufacturers, and opioids sold since at least June of 2009 under the brand names, Exalgo (hydromorphone). Xartemis (oxycodone/acetaminophen) and Roxicodone (oxycodone), (known by the street names “M”, “roxies/roxys” or “blues”). They did so through a highly deceptive marketing campaign that it carried out principally through its sales force and recruited physician speakers. As internal documents indicate, this campaign rested on a series of misrepresentations and omissions regarding the risks, benefits, and superiority of opioids, and incorporated each of the types of deceptive messages described herein. Based on this highly coordinated uniform nature of MALLINCKRODT’s marketing, these deceptive marketing messages were conveyed to New York State and City of Syracuse prescribers and patients. MALLINCKRODT did so with the intent that New York State and City of Syracuse prescribers would rely on these messages in choosing opioids to treat chronic pain.

845. As a part of their deceptive marketing scheme, MALLINCKRODT, along with the Manufacturer Defendants, identified and targeted susceptible prescribers and vulnerable patient populations nationwide and in New York State and in City of Syracuse. For example, MALLINCKRODT, along with the other Manufacturer Defendants, focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and

benefits of opioids and therefore more likely to accept Defendants' misrepresentations.

846. MALLINCKRODT, along with the other Manufacturer Defendants, also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them, and the 2016 CDC guidelines conclude that there are special risks associated with the long-term use of opioids for elderly patients.¹⁷³ The same is true for veterans, who are more likely to use anti-anxiety drugs for post-traumatic stress disorder, which interact dangerously with opioids.

1. MALLINCKRODT's Deceptive Marketing

847. In 2010, MALLINCKRODT sponsored an initiative called “*Collaborating and Acting Responsibly to Ensure Safety*” (C.A.R.E.S.) through which it published and promoted the book “*Defeat Chronic Pain Now!*” aimed at chronic pain patients. The book, which is still available for sale in New York State and elsewhere, and is promoted online at www.defeatchronicpainnow.com advises laypersons who are considering taking opioid drugs that “[o]nly rarely does opioid medication cause a true addiction.”¹⁷⁴ Further the book advises that even the issue of tolerance is “overblown” because “[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance.” In response to a hypothetical question from a chronic pain patient who expresses a fear of becoming addicted, the book advises that “[i]t is very uncommon for a person with chronic pain to become ‘addicted’ to narcotics if (1) he doesn’t have a prior history of any addiction and (2) he only takes the medication to treat pain.”

848. MALLINCKRODT downplayed the severity of opioid detoxification, in its

¹⁷³ 2016 CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016, <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>

¹⁷⁴ Charles E. Argoff & Bradley S. Galer, *Defeat Chronic Pain Now!* (2010)

2010 C.A.R.E.S. publication “*Defeat Chronic Pain Now!*” where they advise potential opioid users that tolerance to opioids can be “easily remedied” and that “[a]ll patients can be safely taken off opioid medication if the dose is slowly tapered down by their doctor.”

849. MALLINCKRODT made false, deceptive and unfair statements to sell more opioid drugs by claiming that opioid dosages could be increased indefinitely without risk. The ability to escalate dosages was critical to MALLINCKRODT’s efforts to market opioids for long term use to treat chronic pain because, absent this misrepresentation, prescribers would have abandoned treatment when their patients built up tolerance and lower dosages did not provide pain relief. In its 2010 C.A.R.E.S. publication “*Defeat Chronic Pain Now!*” potential opioid users are warned about the risk of “[p]seudoaddiction [b]ecause of a [l]ow [d]ose,” and advised that this condition may be corrected through the prescription of a higher dose. Similarly, this book recommends that for chronic pain patients, the opioid dose should be “gradually increased to find the best daily does, as is done with all the other oral drugs.” This book discusses the risks of NSAIDs and other drugs at higher doses, but does not explain this risk for opioids.

850. MALLINCKRODT and other Manufacturer Defendants also offered discounts, known as “chargebacks,” based on sales to certain downstream customers. Distributor Defendants provide information on the downstream customer purchases to MALLINCKRODT and other Manufacturer Defendants to obtain the chargeback.¹⁷⁵

G. ACTAVIS

851. As described herein, ACTAVIS promoted its branded opioid, Kadia, through a highly deceptive marketing campaign that it carried out principally through its sales force and

¹⁷⁵ Press Release, “MALLINCKRODT Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations,” U.S. Dept. of Justice, 11 July 2017. Web. 16 Sept. 2017.

recruited physician speakers. As internal documents indicate, this campaign rested on a series of misrepresentations and omissions regarding the risks, benefits, and superiority of opioids, and incorporated each of the types of deceptive messages described herein. Based on this highly coordinated uniform nature of Actavis' marketing, these deceptive marketing messages were conveyed to New York State and City of Syracuse prescribers and patients. ACTAVIS did so with the intent that New York State and City of Syracuse prescribers would rely on these messages in choosing opioids to treat chronic pain.

852. ACTAVIS also sold generic opioids, including Norco, which was widely prescribed in New York State and in the City of Syracuse and benefited from ACTAVIS' overall promotion of opioids, but these drugs were not directly marketed by sales representatives.

1. ACTAVIS' Deceptive Direct Marketing

853. To help devise its marketing strategy for Kadian, ACTAVIS commissioned a report from one of its consultants in January 2005 about barriers to market entry. The report concluded that two major challenges facing opioid manufacturers in 2005 were (i) overcoming "concerns regarding the safety and tolerability" of opioids, and (ii) the fact that "physicians have been trained to evaluate the supporting data before changing their respective practice behavior." To do that, the report advocated a "[p]ublication strategy based on placing in the literature key data that influence members of the target audience" with an "emphasis ... on ensuring that the message is believable and relevant to the needs of the target audience." This would entail the creation of "effective copy points ... backed by published references" and "developing and placing publications that demonstrate [the] efficacy [of opioids] and [their] safety/positive side effect profile." According to the report, this would allow physicians to "reach[] a mental agreement" and change their "practice behavior" without having first evaluated supporting data of which ACTAVIS (and other Defendants)

had none.

854. The consulting firm predicted that this manufactured body of literature “w[ould], in turn, provide greater support for the promotional message and add credibility to the brand's advocates” based on “either actual or perceived 'scientific exchange'” in relevant medical literature. (emphasis added). To this end, it planned for three manuscripts to be written during the first quarter of 2005. Of these, “[t]he neuropathic pain manuscript will provide evidence demonstrating Kadian is as effective in patients with presumptive neuropathic pain as it is in those with other pain types”; “[t]he elderly sub analysis ... will provide clinicians with evidence that Kadian is efficacious and well tolerated in appropriately selected elderly patients” and will “be targeted to readers in the geriatrics specialty”; and “[t]he QDF/BID manuscript will call attention to the fact that Kadian is the only sustained-release opioid to be labeled for [once or twice daily] use.” In short, ACTAVIS knew exactly what each study would show - and how that study would fit into its marketing plan - before it was published. Articles matching ACTAVIS’ descriptions later appeared in the *Journal of Pain* and the *Journal of the American Geriatrics Society*.

855. To ensure that messages based on this science reached individual physicians, ACTAVIS deployed sales representatives, or detailers, to visit prescribers in New York State and City of Syracuse and across the country. At the peak of ACTAVIS’ promotional efforts in 2011, the company spent \$6.7 million on detailing.

856. To track its detailers' progress, ACTAVIS’ sales and marketing department actively monitored the prescribing behavior of physicians. It tracked the Kadian prescribing activity of individual physicians and assessed the success of its marketing efforts by tabulating how many Kadian prescriptions a prescriber wrote after he or she had been detailed. As described below, Kadian monitored numerous New York State and City of Syracuse physicians.

857. ACTAVIS also planned to promote Kadian by presenting at conferences of organizations where it believed it could reach a high concentration of pain specialists. Its choice of conferences also was influenced by the host's past support of opioids. For example, ACTAVIS documents show that ACTAVIS presented papers concerning Kadian at an annual meeting of AGS because AGS's guidelines "support the use of opioids."

858. ACTAVIS targeted prescribers using both its sales force and recruited physician speakers, as described below.

a. ACTAVIS' Deceptive Sales Training

859. ACTAVIS' sales representatives targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales representatives were critical in delivering ACTAVIS' marketing strategies and talking points to individual prescribers.

860. ACTAVIS' strategy and pattern of deceptive marketing is evident in its internal training materials. A sales education module titled "*Kadian Learning System*" trained ACTAVIS' sales representatives on the marketing messages - including deceptive claims about improved function, the risk of addiction, the false scientific concept of "pseudoaddiction," and opioid withdrawal - that sales representatives were directed and required, in turn, to pass on to prescribers, nationally and in New York State and City of Syracuse.

861. The sales training module, dated July 1, 2010, includes the misrepresentations documented in this Complaint, starting with its promise of improved function. The sales training instructed ACTAVIS' sales representatives that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy," when, in reality, as described above, available data demonstrate that patients on chronic opioid therapy are **less likely** to

participate in daily activities like work. The sales training also misleadingly implied that the dose of prescription opioids could be escalated without consequence and omitted important facts about the increased risks of high dose opioids.

862. First, ACTAVIS taught its sales representatives, who would pass this message on to doctors, that pain patients would not develop tolerance to opioids, which would require them to receive increasing doses: “Although tolerance and dependence do occur with long-term use of opioids, many studies have shown that tolerance is limited in most patients with [Chronic pain].” Second, ACTAVIS instructed its sales personnel that opioid “[d]oses are titrated to pain relief, and so no ceiling dose can be given as to the recommended maximal dose.” ACTAVIS failed to explain to its sales representatives and, through them, to doctors the greater risks associated with opioids at high doses, which are described above.

863. Further, the 2010 sales training module highlighted the risks of alternate pain medications without providing a comparable discussion of the risks of opioids, painting the erroneous and misleading impression that opioids are safer. Specifically, the document claimed that “NSAIDs prolong the bleeding time by inhibiting blood platelets, which can contribute to bleeding complications” and “can have toxic effects on the kidney.” Accordingly, ACTAVIS coached its sales representatives that “[t]he potential toxicity of NSAIDs limits their dose and, to some extent, the duration of therapy” since “[t]hey should only be taken short term.” By contrast, the corresponding section related to opioids neglects to include a single side effect or risk associated with the use of opioids, including from long-term use.

864. This sales training module also severely downplayed the main risk associated with Kadian and other opioids - addiction. It represented that “there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction” and, instead, “[i]t appears likely

that most substance-abusing patients in pain management practices had an abuse problem before entering the practice.” This falsely suggests that few patients will become addicted, that only those with a prior history of abuse are at risk of opioid addiction, and that doctors can screen for those patients and safely prescribe to others. To the contrary, as described above, opioid addiction will affect a significant population of patients, while patients with a history of abuse may be more prone to addiction, all patients are at risk, and doctors may not be able to identify, or safely prescribe to, patients at greater risk.

865. The sales training also noted that there were various “signs associated with substance abuse,” including past history or family history of substance or alcohol abuse, frequent requests to change medication because of side effects or lack of efficacy, and a “social history of dysfunctional or high-risk behaviors, including multiple arrests, multiple marriages, abusive relationships, etc.” This is misleading, as noted above, because it implies that only patients with these kinds of behaviors and history become addicted to opioids.

866. Further, the sales training neglected to disclose that no risk-screening tools related to opioids have ever been scientifically validated. As noted above, the AHRQ recently issued an Evidence Report that could identify “[n]o study” that had evaluated the effectiveness of various risk mitigation strategies - including the types of patient screening implied in ACTAVIS' sales training-on outcomes related to overdose, addiction, abuse or misuse.

867. The sales training module also directed representatives to counsel doctors to be on the lookout for the signs of “[p]seudoaddiction,” which were defined as “[b]ehaviors (that mimic addictive behaviors) exhibited by patients with inadequately treated pain.” However, as described above, the concept of “pseudoaddiction” is unsubstantiated and meant to mislead doctors and patients about the risks and signs of addiction.

868. Finally, the 2010 national training materials trivialized the harms associated with opioid withdrawal by explaining that “[p]hysical dependence simply requires a tapered withdrawal should the opioid medication no longer be needed.” This, however, overlooks the fact, described above, that the side effects associated with opiate withdrawal are severe and a serious concern for any person who wishes to discontinue long-term opioid therapy.

869. The *Kadian Learning System* module dates from July 2010, but ACTAVIS’ sales representatives were passing deceptive messages on to prescribers even before then. A July 2010 “Dear Doctor” letter issued by the FDA indicated that “[b]etween June 2009 and February 2010, ACTAVIS sales representatives distributed ... promotional materials that ... omitted and minimized serious risks associated with [Kadian]”. Certain risks that were misrepresented included the risk of “[m]isuse, [a]buse, and [d]iversion of [o]pioids” and, specifically, the risk that “[o]pioid agonists have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion.” The FDA also took issue with an advertisement for misrepresenting Kadian’s ability to help patients “live with less pain and get adequate rest with less medication,” when the supporting study did not represent “substantial evidence or substantial clinical experience.”

870. ACTAVIS’ documents also indicate that the company continued to deceptively market its drugs after 2010. Specifically, a September 2012 Kadian Marketing Update, and the “HCP Detail” aid contained therein, noted that Kadian’s “steady state plasma levels” ensured that Kadian “produced higher trough concentrations and a smaller degree of peak-to-trough fluctuations” than other opioids.

871. ACTAVIS also commissioned surveys of prescribers to ensure Kadian sales representatives were promoting the “steady-state” message. That same survey - paid for and reviewed

by ACTAVIS - found repeated instances of prescribers being told by sales representatives that Kadian had low potential of abuse or addiction. This survey also found that prescribers were influenced by ACTAVIS' messaging. A number of Kadian prescribers stated that they prescribed Kadian because it was "without the addictive potential" and wouldn't "be posing high risk for addiction." As a result, ACTAVIS' marketing documents celebrated a "perception" among doctors that Kadian had "low abuse potential".

872. Finally, the internal documents of another Defendant, ENDO, indicate that pharmaceutical sales representatives employed by ENDO, ACTAVIS, and PURDUE discussed the AAPM/APS Guidelines with doctors during detailing visits. As discussed above, these guidelines deceptively concluded that the risk of addiction is manageable for patients regardless of past abuse histories.

b. ACTAVIS' Deceptive Speakers Training

873. ACTAVIS also increasingly relied on speakers - physicians whom ACTAVIS recruited to market opioids to their peers - to convey similar marketing messages. ACTAVIS set a goal to train 100 new Kadian speakers in 2008 alone, with a plan to set up "power lunch teleconferences" connecting speakers to up to 500 participating sites nationwide. ACTAVIS sales representatives, who were required to make a certain number of sales visits each day and week, saw the definition of sales call expanded to accommodate these changes, as such calls now included physicians "breakfast & lunch meetings with Kadian advocate/ speaker".

874. A training program for ACTAVIS speakers included training on many of the same messages found in the *Kadian Learning System*. The deceptive messages in ACTAVIS' speakers' training are concerning for two reasons: (a) the doctors who participated in the training were themselves prescribing doctors, and the training was meant to increase their prescriptions of Kadian:

and (b) these doctors were trained, paid, and directed to deliver these messages to other doctors who would write prescriptions of Kadian.

875. Consistent with the training for sales representatives, ACTAVIS' speakers' training falsely minimized the risk of addiction posed by long-term opioid use. ACTAVIS claimed, without scientific foundation, that “[o]pioids can be used with minimal risk in chronic pain patients without a history of abuse or addiction.” The training also deceptively touted the effectiveness of “Risk Tools”, such as the Opioid Risk Tool, in determining the “risk for developing aberrant behaviors” in patients being considered for chronic opioid therapy. In recommending the use of these screening tools, the speakers' training neglected to disclose that none of them had been scientifically validated.

876. The speakers' training also made reference to “pseudoaddiction” as a “[c]ondition characterized by behaviors, such as drug hoarding, that outwardly mimic addiction but are in fact driven by a desire for pain relief and usually signal undertreated pain.” It then purported to assist doctors in identifying those behaviors that **actually** indicated a risk of addiction from those that did not. Behaviors it identified as “[m]ore suggestive of addiction” included “[p]rescription forgery”, “[i]njecting oral formulations”, and “[m]ultiple dose escalations or other non-adherence with therapy despite warnings.” Identified as “[l]ess suggestive of addiction” were “[a]ggressive complaining about the need for more drugs”, “[r]equesting specific drugs”, “[d]rug hoarding during periods of reduced symptoms,” and “[u]napproved use of the drug to treat another symptom.” By portraying the risks in this manner, the speakers' training presentation deceptively gave doctors a false sense of security regarding the types of patients who can become addicted to opioids and the types of behaviors these patients exhibit.

877. The speakers' training downplayed the risks of opioids, while focusing on the risks of competing analgesics like NSAIDs. For example, it asserted that “Acetaminophen toxicity is a

major health concern.” The slide further warned that “Acetaminophen poisoning is the most common cause of acute liver failure in an evaluation of 662 US subjects with acute liver failure between 1998-2003,” and was titled “*Opioids can be a safer option than other analgesics.*” However, in presenting the risks associated with opioids, the speakers’ training focused on nausea, constipation, and sleepiness, and ignored the serious risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness; increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazapines. As a result, the training exaggerated the risks of NSAIDs, both absolutely and relative to opioids, to make opioids appear to be a more attractive first-line treatment for chronic pain.

878. The speakers’ training also misrepresented the risks associated with increased doses of opioids. For example, speakers were instructed to “[s]tart low and titrate until patient reports adequate analgesia” and to “[s]et dose levels on [the] basis of patient need, not on predetermined maximal dose.” However, the speakers’ training neglected to warn speakers (and speakers’ bureau attendees) that patients on high doses of opioids are more likely to suffer adverse events.

2. ACTAVIS’ Deceptive Statements Reached New York State and City of Syracuse Prescribers and Patients

879. The misleading messages and training materials ACTAVIS provided to its sales force and speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients’ pain, without complete and accurate information about the risks, benefits, and alternatives. This deception was national in scope and included New York State and City of Syracuse. As described above, ACTAVIS’ nationwide messages reached New York State and City of Syracuse prescribers in a number of ways. For example, they were carried into New York State and City of Syracuse by ACTAVIS’ sales representatives during detailing visits as well as made available to New York State and City of Syracuse patients and prescribers through websites and ads, including ads in

prominent medical journals. They have also been delivered to New York State and City of Syracuse prescribers by ACTAVIS' paid speakers, who were required by ACTAVIS' policy and by FDA regulations to stay true to ACTAVIS' nationwide messaging.

880. Once trained, ACTAVIS' sales representatives and speakers were directed to, and did, visit potential prescribers in New York State and City of Syracuse, as elsewhere, to deliver their deceptive messages. These contacts are demonstrated by ACTAVIS' substantial effort in tracking the habits of individual New York State and City of Syracuse physicians in prescribing Kadian, and by the direct evidence of ACTAVIS detailing New York State and City of Syracuse prescribers.

881. ACTAVIS tracked, in substantial detail, the prescribing behavior of New York State and City of Syracuse area physicians. It is believed that ACTAVIS has spreadsheets summarizing sales and indicating Kadian prescriptions were written by New York State and City of Syracuse health care providers, which tracks New York State and City of Syracuse area prescribers and measures their current prescribing habits against the volume of Kadian prescriptions they had written in the past, and further analyzes the changes in prescribing behavior so that ACTAVIS could select certain prescribers for detailing visits and other marketing and track the impact of its efforts. It is also believed that ACTAVIS tracks the "top" target prescribers per region.

IX. INSYS Therapeutics and the Systematic Manipulation of Prior Authorization

882. INSYS deceptively marketed its opioid Subsys for chronic and mild pain even though the FDA has expressly limited its use to the treatment of severe cancer pain in opioid tolerant individuals. Subsys is an extremely powerful fentanyl-based sublingual opioid. It is not approved for, and has not been shown to be safe or effective for, chronic or mild pain. Indeed, the FDA expressly prohibited INSYS from marketing Subsys for anything but breakthrough cancer pain in opioid tolerant patients.

883. Despite this, INSYS conducted a well-funded campaign to promote Subsys for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, INSYS used speaker programs, bribed doctors and tricked insurance companies into authorizing Subsys for treating non-cancer patients.

884. Upon information and belief, INSYS aggressively marketed Subsys for uses not approved by the FDA, targeting doctors other than oncologists, including pills mills and pain clinics and promoting the drug for off-label uses like back and neck pain. INSYS sought high-frequency opioid prescribers and pushed them to prescribe larger, more expensive doses.

885. Upon information and belief, INSYS set up a sham speaker program in which doctors – most of whom were not oncologists – were paid for speaking about Subsys at events where sign-in sheets were forged and the guests were often the speaker’s friends and doctors who had already attended similar events. In turn, the speakers were expected to increase their prescriptions of Subsys. INSYS also paid kickbacks and bribes to other physicians for increased prescription rates. Several healthcare providers have pled guilty to prescribing Subsys in exchange for kickbacks and many INSYS employees and former employees – including the former CEO and former vice president of sales – have been charged criminally for the schemes, including bribing health care providers to unnecessarily prescribe Subsys.

886. Upon information and belief, INSYS set up a “reimbursement center” in which its employees called insurers and pharmacy benefit managers and falsely implied or stated that they were with the patient’s health care provider calling to get prior authorization from the payor for the prescription. A prescription for Subsys requires preapproval from the insurance company because the drug is expensive and has such a limited use. Doctors’ offices are supposed to confirm that the patient has cancer, is being treated with an opioid (so is opioid tolerant) and that the patient has unresolved

breakthrough pain. The INSYS employees, pretending to work for the doctor's office, falsely and intentionally implied or stated outright that the patient had cancer when the person did not.

887. These practices allowed INSYS to obtain a 42 percent share of the market for fentanyl- based opioid prescriptions, even though, upon information and belief, in 2016 only 7 percent of the Subsys prescriptions were written by oncologists.

888. On information and belief, INSYS is being investigated by the U.S. Department of Health and Human Services and at least 10 state attorneys general for actions related to its marketing of Subsys. INSYS has already paid settlements to several states following allegations that they provided improper financial incentives to physicians and deceptively marketed Subsys for off-label use.

889. INSYS's deceptive marketing gave doctors and patients the false impression that Subsys was not only safe and effective for treating chronic pain, but was also approved by the FDA for such uses.

A. INSYS "Off Label" Marketing Campaign

890. INSYS orchestrated an "off label" marketing campaign of "Subsys", which is a fast-acting sublingual fentanyl product. Subsys is 100 times stronger than morphine and approved by the FDA to treat cancer patients for "breakthrough" pain. However, INSYS wanted to market Subsys in other ways and developed a very direct and highly profitable marketing campaign that placed "profits over patients" and, as such, they have contributed to the current opioid crisis nationwide, in New York State and City of Syracuse. This resulted in indictments against all members of the pre-2017 INSYS executive board, as well as mid-level managers and sales representatives across the country.

891. It has been alleged that INSYS paid hundreds of thousands of dollars to doctors in

exchange for prescribing a sublingual spray called Subsys that contained the powerful and synthetic opioid fentanyl, which is highly addictive. Three top prescribers have already been convicted of taking bribes from INSYS, along with several sales and marketing representatives having entered plea deals in federal courts across the country.

892. INSYS Therapeutics was co-founded in 2002 by Dr. John Kapoor, a serial pharmaceutical industry entrepreneur “known for applying aggressive marketing tactics and sharp price increases on older drugs.”¹⁷⁶

893. In 2012, INSYS received U.S. Food and Drug Administration (FDA) approval for Subsys, a fentanyl sublingual spray product designed to treat breakthrough cancer pain, and the drug proved incredibly successful financially.¹⁷⁷

894. INSYS had “the best-performing initial public offering in 2013,” and, over the next two years, revenues tripled and profits rose 45%.¹⁷⁸ The value of company stock increased 296% between 2013 and 2016.¹⁷⁹

895. To prevent the over prescription and abuse of powerful and expensive drugs like Subsys, insurers— often using PBMs—employ a process known as prior authorization, which “requires additional approval from an insurer or its pharmacy benefit manager before dispensing. ... Prior authorization policies can also impose ‘step therapy,’ which requires beneficiaries to first use less expensive medications before moving on to a more expensive approach.”¹⁸⁰

¹⁷⁶ *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids*, Wall Street Journal (Nov. 22, 2016) (www.wsj.com/articles/fentanyl-billionaire-comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968).

¹⁷⁷ *Id.*

¹⁷⁸ *Id.*

¹⁷⁹ *An Opioid Spray Showered Billionaire John Kapoor in Riches. Now He’s Feeling the Pain*, Forbes (Oct. 4, 2016) (www.forbes.com/sites/matthewherper/2016/10/04/death-kickbacks-and-a-billionaire-the-story-of-a-dangerous-opioid/).

¹⁸⁰ *Senate Permanent Subcommittee on Investigations, Combating the Opioid Epidemic: A Review of Anti-Abuse Efforts in Medicare and Private Health Insurance Systems* (Oct. 4, 2016); see also Department of Health and Human

896. With regard to INSYS specifically, court filings explain that insurers have “required that a prior authorization be obtained before a claim [can] be submitted for a Subsys® prescription.”¹⁸¹ This process includes “confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys® to treat breakthrough pain that the other opioid could not eliminate. If any one of those factors was not present, the prior authorization would be denied ... meaning no reimbursement would be due.”¹⁸²

897. Shortly after INSYS introduced the drug, these screening processes reportedly raised significant obstacles to Subsys prescriptions. In fact, according to a criminal indictment filed against former INSYS CEO Michael Babich and five other INSYS executives, an internal company analysis in November 2012 revealed that insurers and PBMs approved reimbursements for Subsys in only approximately 30% of cases.¹⁸³

898. In response to these challenges, INSYS allegedly created a prior authorization unit, known at one point as the INSYS Reimbursement Center (IRC), to intervene with PBMs and secure reimbursements between January 2013 and October 2016.¹⁸⁴

899. Led by an INSYS employee named Elizabeth Gurrieri, IRC employees reportedly received significant financial incentives and management pressure—including quotas and group and individual bonuses—to boost the rate of Subsys authorizations.¹⁸⁵

900. According to Patty Nixon, a former INSYS employee and whistleblower, Ms.

Services, Centers for Medicare & Medicaid Services, How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage (MA-PDs) Use Pharmacies, Formularies, & Common Coverage Rules (Oct. 2015).

¹⁸¹ *Complaint (July 12, 2017), Blue Cross of California, Inc., et al. v. INSYS Therapeutics, Inc., D. Ariz. (No. 2:17 CV 02286).*

¹⁸² *Id.*

¹⁸³ *Indictment (Dec. 6, 2016), United States v. Babich, et al., D. Mass. (No. 1:16 CR 10343).*

¹⁸⁴ *See Complaint (July 12, 2017), Blue Cross of California, Inc., et al. v. INSYS Therapeutics, Inc., D. Ariz. (No. 2:17 CV 02286).*

¹⁸⁵ *Murder Incorporated: INSYS Therapeutics, Part I, Southern Investigative Reporting Foundation (Dec. 3, 2015) (sirf-online.org/2015/12/03/murder-incorporated-the-INSYS-therapeutics-story/); see also Indictment (Dec. 6, 2016), United States v. Babich, et al., D. Mass. (No. 1:16 CR 10343).*

Gurrieri personally pressured IRC employees to improve the rate of prescription approvals, noting that “Dr. Kapoor’s not happy, we have to get these approvals up.”¹⁸⁶

901. IRC employees allegedly met this demand through a number of techniques. Employees, for example, reportedly falsified medical histories for prospective Subsys patients, “fraudulently assert[ing] that a patient had a cancer diagnosis regardless of the patient’s history and regardless of whether the prescriber had prescribed Subsys® for a different diagnosis.”¹⁸⁷

902. In response to increased scrutiny from PBMs and the U.S. Department of Health and Human Services, INSYS allegedly developed a canned response to questions concerning whether a potential Subsys patient suffered from breakthrough cancer pain. In this response, INSYS employees stated that “[t]he physician is aware that the medication is intended for the management of breakthrough pain in cancer patients [and] [t]he physician is treating the patient for their pain (or breakthrough pain, whichever is applicable).”¹⁸⁸

903. According to an affidavit filed in support of criminal charges against Ms. Gurrieri, the script “deliberately omitted the word ‘cancer’ in order to mislead agents of insurers and PBMs.”¹⁸⁹ The IRC also allegedly misled PBMs and insurers about the unit’s role in facilitating approvals for Subsys.¹⁹⁰ To prevent PBMs from tracing calls back to INSYS, for example, the IRC obscured its outgoing phone number on caller ID.¹⁹¹ When PBMs required a phone number for a return call, INSYS employees reportedly provided a 1-800 number manned by another INSYS

¹⁸⁶ *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids*, Wall Street Journal (Nov. 22, 2016).

¹⁸⁷ *Complaint* (7/12/17), *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc.*, D. Ariz. (No. 2:17 CV 02286).

¹⁸⁸ *Indictment* (Dec. 6, 2016), *United States v. Babich, et al.*, D. Mass. (No. 1:16 CR 10343).

¹⁸⁹ *Affidavit of Special Agent Paul S. Baumrind, Federal Bureau of Investigation, In Support of a Criminal Complaint and Arrest Warrant* (Oct. 12, 2016), *United States v. Gurrieri*, D. Mass. (No. 1:17 CR 10083); see also *Complaint* (July 12, 2017), *Blue Cross of California, Inc., et al. v. INSYS Therapeutics, Inc.*, D. Ariz. (No. 2:17 CV 02286).

¹⁹⁰ *Indictment* (Dec. 6, 2016), *United States v. Babich, et al.*, D. Mass. (No. 1:16 CR 10343).

¹⁹¹ *Murder Incorporated: INSYS Therapeutics, Part I*, Southern Investigative Reporting Foundation (Dec. 3, 2015); see also *Indictment* (Dec. 6, 2016), *United States v. Babich, et al.*, D. Mass. (No. 1:16 CR 10343).

representative—instead of contact information for the prescribing physician.¹⁹² INSYS executives also allegedly told IRC employees to claim they were calling “from” a physician’s office; later, “employees were instructed to tell agents of insurers and pharmacy benefit managers that they were calling ‘on behalf’ of a specific doctor, and were ‘with’ a specific doctor’s office.”¹⁹³

904. Former INSYS sales representative, Patty Nixon, turned whistleblower, claims the company lured doctors into prescribing the drug for patients who didn’t need it, known as “off-label” marketing. Ms. Nixon claims she was trained and instructed by INSYS to make sure Subsys got into the hands of as many patients as possible, whether they had cancer or not, and this included using illegal and unethical methods of getting doctors to write massive numbers of Subsys prescriptions for questionable pain complaints. She claims, her job responsibilities included contacting insurance companies on behalf of patients and doctors to get the medication approved and paid for by their insurance company. In fact, the role of the IRC was to make sure that patients got approval for Subsys, which includes fentanyl, from insurance companies. “The unit job responsibilities were to contact insurance companies on behalf of the patients and the doctors to get the medication approved and paid for by their insurance company,” said Patty Nixon.

905. Subsys is not cheap prescription, a 30-day supply costs anywhere from \$3,000 to \$30,000 and the fraudulent scheme depended upon insurance approval, which Ms. Nixon claims was her job, along with the other employees in the Reimbursement Unit, who were tasked with the role of misleading insurers into believing the drug was “medically necessary.”

906. Ms. Nixon claims she would, using the IRC’s management created insurance script, make telephone calls to insurance companies telling them she was from a physician’s office and requesting prior authorization for the medication called Subsys.

¹⁹² *Murder Incorporated: INSYS Therapeutics, Part I*, Southern Investigative Reporting Foundation (Dec. 3, 2015).

¹⁹³ *Indictment* (Dec. 6, 2016), *United States v. Babich, et al.*, D. Mass. (No. 1:16 CR 10343).

907. According to Ms. Nixon, the Reimbursement Unit staff would often pretend they were calling from the office of a cancer doctor to increase the chances of approval, as well as using specific diagnosis codes, likely to be approved, whether the patient had the condition or not. “We told complete bold-faced lies” as part of the part of the ongoing fraudulent INSYS business model, stated Ms. Nixon.

908. According to a class action lawsuit, INSYS management “was aware that only about 10% of prescriptions approved through the Prior Authorization Department were for cancer patients,” and an Oregon Department of Justice investigation found that 78% of preauthorization forms submitted by INSYS on behalf of Oregon patients were for off-label uses.¹⁹⁴ In just one example, an Anthem review of Subsyst claims “revealed that 54% of members with Subsyst® prescriptions that had been reimbursed by Anthem did not actually have an underlying cancer diagnoses,” and “[f]or an additional 6% of members with reimbursed Subsyst® prescriptions, it was unclear whether Subsyst® was properly prescribed.”¹⁹⁵ Anthem estimates that it “paid over \$19 million in reimbursements for Subsyst® prescriptions that were not covered by Anthem’s plans.”¹⁹⁶

909. Internal INSYS documents suggest the company knew that the IRC lacked formal policies or monitoring procedures to ensure proper communication between INSYS employees and healthcare professionals. INSYS, in other words, lacked even basic measures to prevent its employees from manipulating the prior authorization process and received clear notice of these deficiencies.

910. In an internal presentation dated 2012 and entitled, “2013 SUBSYS Brand Plan,”

¹⁹⁴ *The Pain Killer: A Drug Company Putting Profits Above Patients*, CNBC (Nov. 4, 2015) (www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-INSYSpharmaceuticals.html).

¹⁹⁵ *Complaint* (July 12, 2017), *Blue Cross of California, Inc., et al. v. INSYS Therapeutics, Inc., D. Ariz.* (No. 2:17 CV 02286).

¹⁹⁶ *Id.*

INSYS identified one of six “key strategic imperatives” as “Mitigate Prior Authorization barriers.”¹⁹⁷

On a later slide, the company identified several tasks associated with this effort, including “Build internal [prior authorization] assistance infrastructure,” “Establish an internal 1-800 reimbursement assistance hotline,” and “Educate field force on [prior authorization] process and facilitation.”¹⁹⁸

911. Additional materials produced by INSYS to the U.S. Senate Homeland Security & Governmental Affairs Committee, minority staff suggest, however, that INSYS did not match these efforts with sufficient compliance processes to prevent fraud and was internally aware of the danger of problematic practices. Specifically, on February 18, 2014, Compliance Implementation Services (CIS)—a healthcare consultant—issued a draft report to INSYS titled, “INSYS Call Note, Email, & IRC Verbatim Data Audit Report.”¹⁹⁹ The introduction to the report explained that “CIS was approached by INSYS’ legal representative ... on behalf of the Board of Directors for INSYS to request that CIS support in review of certain communications with Health Care Professionals (HCPs) and INSYS employees, and report how there were being documented.”²⁰⁰ INSYS had expressed concerns “with respect to communications with HCPs by INSYS employees being professional in nature and in alignment with INSYS approved topics regarding off or on-label promotion of an INSYS product, and general adherence to INSYS documentation requirements.”²⁰¹ An additional concern “stemmed from the lack of monitoring of commercial activities where these types of interactions could occur.”²⁰²

912. Given these issues, INSYS requested that CIS review—in part—“the general

¹⁹⁷ *INSYS Therapeutics, Inc., 2013 Subsys Brand Plan, 2012 Assessment (2012) (INSYS_HSGAC_00007472).*

¹⁹⁸ *Id. at INSYS_HSGAC_00007473.*

¹⁹⁹ *Compliance Implementation Services, INSYS Call Note, Email & IRC Verbatim Data Audit Report (Feb. 18, 2014) (INSYS_HSGAC_00007763).*

²⁰⁰ *Id. at INSYS_HSGAC_00007765.*

²⁰¹ *Id.*

²⁰² *Id.*

communications from the INSYS Reimbursement Center (IRC) to HCPs, their office staff or representatives, as well as health insurance carriers ... to ensure they were appropriate in nature with respect to specific uses of SUBSYS, INSYS' commercially marketed product.”²⁰³

913. According to the findings CIS issued, INSYS lacked formal policies governing the actions of its prior authorization unit. For example, “[n]o formal and approved policy on appropriate communications between IRC employees and HCPs, their staff, [health care insurers (HCIs)], or patients exists...that governs the support function of obtaining a prior authorization for the use of SUBSYS.”²⁰⁴ In addition, the report noted that “there were also gaps in formally approved foundational policies, procedures, and [standard operating procedures] with respect to required processes specifically within the IRC.”²⁰⁵ In fact, “[t]he majority of managerial directives, changes to controlled documents or templates, as well as updates or revisions to processes were not formally approved, documented, and disseminated for use, and were sent informally via email blast.”²⁰⁶ Although four informal standard operating procedures existed with regard to IRC functions, these documents “lacked a formal review and approval” and failed to “outline appropriately the actions performed within the IRC.”²⁰⁷

914. The report also explains that INSYS lacked procedures for auditing interactions between IRC employees and outside entities. According to CIS, “no formal, documented, or detailed processes by which IRC representatives’ calls via telephone were audited for proper communication with HCPs or HCIs in any fashion [existed] other than random physical review of a call in a very

²⁰³ *Id*

²⁰⁴ *Id. at INSYS_HSGAC_00007770*

²⁰⁵ *Id. at INSYS_HSGAC_00007768*

²⁰⁶ *Id. at INSYS_HSGAC_00007771*

²⁰⁷ *Id. at INSYS_HSGAC_00007770*

informal and sporadic manner.”²⁰⁸ More broadly, the report notes that “no formal and documented auditing and monitoring or quality control policy, process, or function exists between IRC employee communications and HCPs, HCP staff, HCIs, or patients.”²⁰⁹

915. At the end of the report, CIS provided a number of recommendations concerning IRC activities. First, CIS suggested that IRC management “formally draft and obtain proper review and approval of an IRC specific policy detailing the appropriate communications that should occur while performing the IRC associate job functions and interacting with HCPs.”²¹⁰ Similarly, IRC management was urged to formally draft IRC-specific standard operating procedures “specific to each job function within the IRC,” accompanied by “adequate training and understanding of these processes.”²¹¹ To ensure compliance with IRC standards, INSYS was also directed to create an electronic system to allow management “to monitor both live and anonymously IRC employee communications both incoming and outgoing.”²¹² Finally, CIS recommended that INSYS institute a formal process for revising and updating “IRC documentation used for patient and HCP data.”²¹³

916. The CIS report concluded by noting, in part, that a review of ten conversations between IRC employees and healthcare providers, office staff, and insurance carriers revealed “that all IRC staff was professional in communication, and in no instance was inaccurate or off-label usage of SUBSYS communicated.”²¹⁴ Yet within a year of this conclusion, according to the recording transcribed below, an INSYS IRC employee appears to have misled a PBM representative regarding the IRC employee’s affiliation and the diagnosis applicable to Sarah Fuller, with death as the alleged

²⁰⁸ *Id.* at INSYS_HSGAC_00007769

²⁰⁹ *Id.* at INSYS_HSGAC_00007771

²¹⁰ *Id.* at INSYS_HSGAC_00007770

²¹¹ *Id.* at INSYS_HSGAC_00007771.

²¹² *Id.*

²¹³ *Id.*

²¹⁴ *Id.* at INSYS_HSGAC_00007772.

result due to inappropriate and excessive Subsys prescriptions.

917. As part of an investigation, the U.S. Senate Homeland Security & Governmental Affairs Committee, minority staff, staff received an audio recording of conversations between an INSYS employee and PBM representatives related to a Subsys prescription for Sarah Fuller, who later died from an alleged fentanyl overdose.²¹⁵ This recording suggests the IRC employee in question repeatedly misled Envision Pharmaceutical Services to obtain approval for Subsys treatment for Ms. Fuller. The recording reveals that the INSYS employee identified herself as being “with” the office of Ms. Fuller’s doctor; in the second conversation, the employee confirms she is “calling from the doctor’s office.” The INSYS employee also states that Subsys is “intended for the management of breakthrough cancer pain” without explicitly claiming that Ms. Fuller suffers from this type of pain. She then states that Ms. Fuller suffers from breakthrough pain—pointedly dropping “cancer” from the description. Later, when asked whether the Subsys prescription will treat “breakthrough cancer pain or not,” the INSYS employee sidesteps the question by merely stating there is “no code for breakthrough cancer pain.” She then reaffirms that the prescription is “for breakthrough pain, yeah.”

918. According to public reporting, lawsuits from Subsys patients, and criminal indictments, INSYS Therapeutics has repeatedly employed aggressive and likely illegal techniques to boost prescriptions for its fentanyl product Subsys.

919. The U.S. Senate Homeland Security & Governmental Affairs Committee, minority staff, as part of their investigation, has concluded that the audio recording of the INSYS’

²¹⁵ *Fuller v. Matalon, et. al.*, filed in Superior Court of Middlesex County, New Jersey, on March 23, 2017 (No. L1859-17), is a civil complaint that alleges Sarah A. Fuller died from a Subsys overdose on March 25, 2016. According to the Complaint, in January 2015, Ms. Fuller met with Dr. Matalon, her father and an INSYS representative to discuss Subsys as a remedy for her neck and back pain; however, she was not informed that Subsys was fentanyl and approved and indicated only for patients experiencing breakthrough cancer pain from malignant cancer. Over the next few months, Ms. Fuller received increasing amounts of Subsys on a monthly basis and was even admitted to a local hospital in October of 2015, suffering from “hyper-sedation with hypoxia secondary to narcotics and sedatives.” Notwithstanding instructions to discontinue Subsys, Ms. Fuller received additional Subsys prescriptions, along with prescriptions for Percocet, Oxycontin, and Alprazolam, over the next five months until her death in March of 2016.

Representative that misled the PBM to obtain prior authorization for Sarah Fuller, as discussed above, and other materials they reviewed, suggests INSYS' efforts have included actions to undermine critical safeguards in the prior authorization process—with INSYS officials aware, at the very least, of the serious danger of these acts occurring.

920. The PBM Express Scripts excluded Subsys from its list of covered drugs in 2015, and UnitedHealth Group, which owns the PBM OptumRx, did the same in 2016.²¹⁶

921. In December 2016, federal prosecutors indicted Mr. Babich and five other former INSYS executives on racketeering charges, alleging that these individuals “approved and fostered” fraudulent prior authorization practices.²¹⁷ In June 2017, Ms. Gurrieri, the former head of the IRC, pled guilty “to having conspired to defraud insurers.”²¹⁸

922. On October 26, 2017, the founder of INSYS and billionaire, Dr. Johnathon N. Kapoor, was arrested and charged with leading a massive conspiracy across the United States to pay bribes and use fraudulent sales methods in the illegal distribution of Subsys, a fentanyl spray intended for cancer patients. Dr. Kapoor, of Phoenix, Arizona, the former Chairman-CEO of INSYS and still a member of its board, was indicted on federal charges of racketeering, conspiracy to commit fraud and conspiracy to violate the Anti-Kickback law.

923. Dr. Kapoor's indictment originated in federal court in Boston. Acting United States Attorney William D. Weinreb of Massachusetts, stated, “In the midst of a nationwide opioid epidemic that has reached crisis proportions, Mr. Kapoor and his company stand accused of bribing doctors to overprescribe a potent opioid and committing fraud on insurance companies solely for profit ... Today's arrest and charges reflect our ongoing efforts to attack the opioid crisis from all

²¹⁶ *The Pain Killer: A Drug Company Putting Profits Above Patients*, CNBC (Nov. 4, 2015)

²¹⁷ *Indictment* (Dec. 6, 2016), *United States v. Babich, et al.*, D. Mass. (No. 1:16 CR 10343).

²¹⁸ *Ex-INSYS Employee Pleads Guilty in U.S. Opioid Drug Probe*, Reuters (June 19, 2017) (www.reuters.com/article/us-INSYS-court-idUSK8N19A2MB).

angles. We must hold the industry and its leadership accountable.

X. Manufacturer Defendants Knew Their Marketing Was False, Unfounded, Dangerous, and Would Harm Plaintiffs.

924. Manufacturer Defendants made, promoted, and profited from their misrepresentations—individually and collectively—knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic pain were false and misleading. CEPHALON and PURDUE entered into settlements in the hundreds of millions of dollars to resolve criminal and federal charges involving nearly identical conduct.

925. Manufacturer Defendants expected and intended that their misrepresentations would induce doctors to prescribe, patients to use, and payors to pay for their opioids for chronic pain.

926. When they began their deceptive marketing practices, Manufacturer Defendants recklessly disregarded the harm that their practices were likely to cause. As their scheme was implemented, and as the reasonably foreseeable harm began to occur, Manufacturer Defendants knew that it was occurring. Manufacturer Defendants closely monitored their own sales and the habits of prescribing doctors, which allowed them to see sales balloon—overall, in individual practices, and for specific indications. Their sales representatives knew what types of doctors were receiving their messages and how they were responding. Moreover, Manufacturer Defendants had access to, and carefully monitored government and other data that tracked the explosive rise in opioid use, addiction, injury, and death.

XI. Manufacturer Defendants Fraudulently Concealed Their Misrepresentations.

927. Manufacturer Defendants tried to avoid detection of their deceptive marketing and conspiratorial behavior, and tried to fraudulently conceal their strategies.

928. Manufacturer Defendants disguised their own roles in the deceptive marketing by

funding and working through Front Groups purporting to be patient advocacy and professional organizations and through paid KOLs. Manufacturer Defendants purposefully hid behind the assumed credibility of the front organizations and KOLs and relied on them to vouch for the accuracy and integrity of Manufacturer Defendants' false and misleading statements about opioid use for chronic pain.

929. Manufacturer Defendants did not disclose their role in shaping, editing, and approving the content of the Front Groups publications. Manufacturer Defendants secretly influenced these purportedly "educational" or "scientific" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies.

930. Besides hiding their own role in generating the deceptive content, Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear these items were accurate, truthful, and supported by substantial scientific evidence. Manufacturer Defendants distorted the meaning or import of materials they cited and offered them as evidence for propositions the materials did no support. The true lack of support for Manufacturer Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions. The false and misleading nature of Manufacturer Defendants' marketing was not known to, nor could it reasonably have been discovered by, Plaintiff or their residents.

931. Manufacturer Defendants also concealed their participation by extensively using the public relations companies they hired to work with Front Groups to produce and disseminate deceptive materials.

932. Manufacturer Defendants concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the existence of claims that Plaintiffs now assert. Plaintiffs did not discover the existence and scope of Manufacturer Defendants' industry-wide

fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

933. Through the public statements, marketing, and advertising, Manufacturer Defendants' deceptions deprived Plaintiffs of actual or implied knowledge of facts sufficient to put them on notice of potential claims.

XII. Manufacturer Defendants' False Representations to Managed Care Plans

934. No amount of patient and doctor enthusiasm for the 'breakthrough' treatment of chronic pain mattered if there was no health plan prepared to pay for it. Gaining both access to and preferred placement on Third Party Payors' formularies was thus a priority; and for this the Manufacturer Defendants would enlist the help of the Distributor and the Pharmacy Defendants. Ensuring formulary access was part of all Defendants' efforts to expand the opioid drug market. All of the Defendants engaged in a formulary access and coverage enterprises scheme, as discussed herein.

935. The Manufacturer Defendants understood how prescribing health care professionals were more likely to prescribe opioid drugs if covered on a formulary. And the Manufacturer Defendants further understood how Third Party Payors made coverage decisions, and devised schemes to influence that process.

936. Given the mechanics of prescription drug reimbursement, Third Party Payors, including, self-funded health and prescription plans, were harmed financially by Defendants' fraudulent schemes. As alleged below, Third Party Payors, including self-funded health and prescription plans, were targets of Defendants' unlawful strategies aimed at Plaintiff's employee(s) and retiree(s) and their dependent(s) members and its self-funded customers' members, which successfully resulted in excessive and unnecessary prescriptions for the opioid drugs and giving rise

to its direct economic claims set forth herein.

937. As alleged in detail below in the formulary access and coverage enterprises for each Manufacturer Defendant, each of the Defendant's strategic plans included multi-pronged targeting of Third Party Payors. As alleged herein, Defendants' common tactics included comprehensive business plans that carefully tracked Third Party Payors' coverage decisions – e.g., whether one or more opioid drugs was on formulary, what tier, and any restrictions.

938. As alleged in detail below in the formulary access and coverage enterprises for each Manufacturer Defendant, each of the Defendant's strategic plans included multi-pronged targeting of Third Party Payors. As alleged herein, Defendants' common tactics included comprehensive business plans that carefully tracked Third Party Payors' coverage decisions – e.g., whether one or more opioid drugs was on formulary, what tier, and any restrictions.

939. As alleged herein below, the Defendants' direct misleading promotion aimed at Third Party Payors and their employees, including in face-to-face meetings with Defendants' managed care account executives, involved the misrepresentations in the scheme alleged as the formulary access and coverage enterprises, herein. These misrepresentations were embraced and shared by each Manufacturer Defendant. Each was aware that Third Party Payors wanted to control access to the opioid drugs on its formularies. To circumvent these controls, Defendants planned and implemented false and misleading marketing campaigns to target Third Party Payors to ensure formulary access for the opioid drugs without limitation, including for unsafe and unapproved uses.

940. To execute their formulary access and coverage enterprises successfully, each Manufacturer Defendant provided Third Party Payors' managed pharmaceutical personnel directly, through intermediaries, and/or through marketing (including Scientific Literature Marketing Enterprise publications), materials that discussed or suggested that the opioid drugs were safe and/or

effective for the long-term treatment of chronic pain. Third Party Payors relied on these materials in making coverage and formulary placement decisions.

941. Further, concepts such as “pseudoaddiction” were key not only to increasing prescriber demand, but important for securing formulary access. Had the Manufacturer Defendants not pushed the notion of “pseudoaddiction” - that addiction was not really addiction - there would have been far more addiction-related adverse events reported with respect to the opioid drugs. This in turn would have impacted Third Party Payors and/or its contracted pharmacy benefit managers’ review of opioid drugs with respect to both formulary access and preferred status, compared to other painkillers that would have exhibited a lower rate of addiction-related adverse events.

942. Similarly, the Manufacturer Defendants also advised prescribers of “techniques” to ensure health plan reimbursement. These included both the way opioid drugs were prescribed (amount vs. frequency of dosage) and the reported conditions for which they were prescribed in the first place. Upon reasonable belief, physicians writing opioid drug prescriptions reimbursed by Third Party Payors utilized these techniques.

A. Background Regarding Third Party Payors and Prescription Drug Coverage

943. Although the physician prescribes the opioid drugs, it is the patients and their Third Party Payors’ insurance company which pay their costs. Third Party Payors generally pay 75-90% of the retail cost of brand name drugs, while the patient is responsible for a small copayment. The physician bills the patient’s insurance company for associated office visits.

944. Absent prescription drug coverage, patients are responsible for paying 100% of the cost of their prescribed opioid drugs. Physicians were either opposed or reluctant to prescribe opioid drugs if their patients were responsible for money out of pocket when the opioid drugs were not “on formulary” (or were but with very high copayments or restrictions).

945. The formulary is a list of medications that have been selected for the purpose of encouraging quality and cost-effective prescribing of pharmaceuticals within a patient population. Formularies are segmented by the therapeutic uses of the drugs, and opioid drugs are classified as Narcotic Analgesics on Third Party Payors' formulary.

946. In addition to the formulary, Third Party Payors often limit coverage of some classes of medication based on the conditions being treated.

947. Third Party Payors can utilize their formulary (and corresponding higher or lower copays) to promote compliance with national treatment guidelines, to discourage undocumented or non-medical uses of drug therapies, and to educate prescribers regarding the cost-effectiveness of drug treatment options.

948. The decision whether to place a given pharmaceutical product on a drug formulary is first and foremost a clinical decision. The Third Party Payors will review the FDA approved clinical indications for the product or products in question and FDA comments associated with the approval of the products. The Third Party Payors rely on published studies and other materials that evaluate product efficacy, safety and, when available, directly compare the product to other agents in the appropriate therapeutic category or with comparable clinical uses.

949. Manufacturers often submit a formulary dossier and other materials about their drug products for use by Third Party Payors during the drug review process. The Third Party Payors will also review any existing utilization of the product, or of comparable products, by health plan members. The Third Party Payors's evaluations are limited to a review of published medical information, such as clinical studies published in peer-reviewed articles and the formulary dossier provided by the manufacturer, and drug utilization data.

950. Defendants knew that gaining prescription drug coverage, as well as favorable

formulary status, was essential to both growing the entire market for opioids as well as the sales of their respective opioid drugs, as physicians based their prescribing on the opioid drugs formulary coverage.

951. Third Party Payors provide medical and pharmacy benefits to a wide range of organizations nationally, including employers, state and local governments and Medicaid programs through insurance contracts and through self-funded contracts with employers.

952. Opioid drugs have been widely accepted on the formularies used by Third Party Payors and are subject to modest branded cost sharing requirements. Third Party Payors and/or their contracted pharmacy benefit managers have relied on various representations and omissions made by Defendants regarding the addictiveness (or lack thereof) of opioid drugs to provide formulary access. Due to Defendants' misrepresentations regarding addictiveness and concealment of drug diversion evidence, Third Party Payors, including self-funded health and prescription plans, were led to believe that opioid drugs were clinically safe and effective.

953. Prior authorization is a drug management tool that is used by Third Party Payors when the drug coverage process requires information that cannot be readily obtained through the claim processing system. Such criteria may include diagnosis, laboratory values or other clinical parameters. For example, a health plan may wish to cover opioid drugs for the treatment of acute cancer-related pain, but would wish to exclude opioid drugs when they are being prescribed for the treatment of chronic pain. When a prior authorization is applied, the claim is rejected at the pharmacy and the pharmacist is notified that the prescriber must contact the Third Party Payor or its contracted pharmacy benefit manager to obtain approval for coverage, much in the same manner that pre-certification is required for the use of certain health care services.

954. Third Party Payors (and/or their contracted pharmacy benefit managers) don't

typically have access to the patient's diagnosis as a component of the claim transaction. As such, Third Party Payors don't know the reasons (whether for long-term chronic pain or acute cancer-related pain) for which opioid drugs are being prescribed when claims are being processed. As a result, a diagnosis code is not included as a component of typical claim transactions and is unknown to Third Party Payors and/or contracted pharmacy benefit managers.

955. The Defendants' misrepresentations and concealment of drug diversion evidence, which Defendants were legally obligated to report, but failed to do so, interfered with Third Party Payors' requiring strict formulary control, such as prior authorizations, step edits, and days quantity supply limits.

956. Third Party Payors make decisions, based on FDA approvals, manufacturer-supplied information and clinical studies, to include or exclude new or existing prescription drugs from its formulary, or to implement tools to control utilization or to modify coverage criteria.

957. Third Party Payors have relied on Manufacturer Defendants misrepresentations that have impacted their formulary drug coverage criteria recommendations, including, by the Defendants. For example, the Manufacturer Defendants' false and misleading information, such as citations to Manufacturer Defendant-sponsored and Front Group or KOL written treatment guidelines and articles and Manufacturer Defendant-sponsored studies, have included: (i) Chou R, Fanciullo GJ, Fine PG, et al., American Pain Society - American Academy of Pain Medicine Opioids Guidelines Panel, *Clinical guidelines for the use of chronic opioid therapy in chronic non-cancer pain*, J. Pain. 2009;10(2):113-30; (ii) Roper Starch Worldwide for the American Academy of Pain Medicine, American Pain Society, and Janssen Pharmaceutica, *Chronic Pain in America: Roadblocks to Relief*, 1999; and (iii) Gordon DB, Dahl JL, Miaskowski C, et al., *American Pain Society quality of care task force.*, Arch Intern Med. 2005;165(14):1574-80. Other false and misleading information from the

Manufacturer Defendants (or those of their KOLs or Front Groups, have included, (i) Raffa BR, Pergolizzi JV, *Opioid formulations designed to resist / deter abuse*, *Drugs*, 2010;70(13):1657-1675; (ii) Chou R, Fanciullo GJ, Fine PG, et al., American Pain Society – American Academy of Pain Medicine Opioids Guidelines Panel, *Clinical guidelines for the use of chronic opioid therapy in chronic non-cancer pain*, *J. Pain*. 2009;10(2):113-30; (iii) American Pain Society, *Guidelines for the use of chronic opioid therapy in chronic non-cancer pain* (2009); and (iv) Taylor DR, Webster LR, Chun SY, et al., *Impact of breakthrough pain on quality of life in patients with chronic, non- cancer pain; patient perceptions and effect of treatment with oral transmucosal fentanyl citrate* (OTFC, ACTIQ), *Pain Med*. 2007;8(3):281-288. It is believed that Third Party Payors had access to and/or received these and other Defendant-sponsored studies and articles and relied on them when making formulary status determinations with respect to the opioid drugs.

958. It was not until after the issuance of the 2016 CDC Guidelines illuminating Defendants' misrepresentations, that Third Party Payors began to implement formulary management utilization tools to further restrict and limit opioid drug product coverage.

959. It is believed that each and every Defendant, through its various enterprises, targeted Third Party Payors with false and misleading statements in order to secure formulary status for the opioid drugs. It is further believed that Manufacturer Defendants' common tactics included comprehensive business plans that carefully tracked Third Party Payors coverage decisions – *e.g.*, whether one or more of the opioid drugs was on formulary, what tier, and any restrictions.

960. As alleged herein, the Manufacturer Defendants' direct misleading promotion aimed at Third Party Payors and its employees, including in face-to-face meetings with Defendants' managed care account executives, involved the misrepresentations as alleged in the scheme known as the formulary access and coverage enterprises. These misrepresentations were embraced and shared

by each Defendant. Defendants were aware that Third Party Payors wanted to restrict availability of highly addictive opioid medications to those suffering from cancer pain. Defendants were further aware that healthcare and related costs associated with opioid use was of paramount importance to Third Party Payors. To circumvent these concerns, Defendants planned and implemented false and misleading marketing campaigns to target Third Party Payors to ensure formulary access for chronic non-cancer pain and other conditions, (notwithstanding lack of evidence of safety or efficacy) – e.g., misrepresentations that the opioid drugs were effective over the long-term and would not result in addiction, withdrawal or other serious safety risks, when knowing the opposite was true.

961. All Defendants were also aware that the growing evidence of opioid drug diversion—*i.e.*, the burgeoning black market for opioid drugs—would have led Third Party Payors to make decisions that would have drastically reduced the opioid drugs’ access to Third Party Payors’ formulary, or led Third Party Payors to implement controls that would have prevented drug diversion. However, all Defendants were making significant money from the opioid drug market, and suppressed non-cancer evidence of diversion so as to maintain formulary access and status for opioid drugs.

962. In an effort to maintain favorable formulary status for opioid medications, Defendants employed the misrepresentations alleged herein. Defendants were fully aware of Third Party Payors’ concerns over rising healthcare costs, and aimed to score formulary coverage for their abuse-deterrent formulations by overly stating the effectiveness against abuse and addiction and presenting misleading information on the healthcare cost savings with abuse-deterrent and extended-release formulations to Third Party Payors.

963. It is believed that Third Party Payors are regular recipients of periodicals, sent through the mails and through electronic delivery through the wires, both in interstate commerce,

which include information relevant to management of the pharmacy benefit for their members. These periodicals include the AMCP Daily Dose, Journal of Clinical Pathways, First Report Managed Care, the Journal of Clinical Outcomes Management (“JCOM”), Managed Healthcare Executive, The American Journal of Managed Care, The American Journal of Pharmacy Benefits (“AJPB”), American Health & Drug Benefits, and Pharmacy Times. It was believed that these were reputable publications that could be relied upon by Third Party Payors as part of gathering relevant information in their opioid coverage decision making.

964. Defendants utilized these and other managed care periodicals to disseminate their false and misleading messages concerning opioid drugs to Third Party Payors. Many of Defendants’ marketing messages appeared in these publications.

B. Formulary Access and Coverage Enterprises/Schemes

1. PURDUE’s False and Misleading Messages to Third Party Payors

965. As part of PURDUE’S formulary access and coverage enterprise, it developed a dedicated “managed care” (also called “Regional Account Executives” or “Managed Markets”) sales group, many of whom had advanced science degrees, whose job it was to call on Third Party Payor pharmacy directors and personnel. It is believed that these specialized Managed Markets representatives presented false and misleading studies/abstracts to Third Party Payors, including, self-funded health and prescription benefit plans, to influence placement of PURDUE’s drugs on its formularies.

966. Some misrepresentations made to prescribers were more about securing health plan coverage than about increasing prescriber demand. For example, PURDUE’s misleading focus on 12-hour dosing (where sales representatives pleaded with physicians to increase dosage rather than shorten dosing intervals) was motivated almost solely with insurance coverage in mind. PURDUE

feared managed care companies would not provide coverage for more frequent dosing intervals and knew higher dosages equated more profits. In a 2001 workshop presentation, Purdue expressed concerns that managed care companies would “deny[] or will start denying shorter prescriptions.”²¹⁹ And according to Purdue’s own 2001 sales data, the company charged on average about \$97 for a bottle of the 10-milligram pills, the smallest dosage, while the maximum strength, 80 milligrams, ran more than \$630.”²²⁰ Moreover, Purdue sales representatives were told that “raising dosage strength was the key to a big payday” as bonuses and performance evaluations “were based in part on the proportion of sales from high-dose pills.”²²¹

967. As noted extensively above, PURDUE sponsored studies and publications containing deceptive statements as to the efficacy, safety and healthcare cost savings of opioid drug products often appeared in AMCP publications circulated to Third Party Payors. One example of a publication touting the health care savings managed care would experience with abuse-deterrent formulations in AMCP’s Daily Dose, upon information and belief, was sent via email to Third Party Payors’ personnel. The AMCP publication highlighted an article from the Boston Business Journal entitled *Analyst Says Abuse-Resistant Opioid Painkiller Helps Save Millions of Dollars*. The article stated that “research suggests ‘that such a [ADF] reformulation would not only reduce addiction, but also save millions in national healthcare costs.’” More specifically, “\$430 [million] a year because of reformulation of another opioid OxyContin.”

968. Third Party Payors relied on these and other statements when making decisions regarding the access to and status of Opioid Drugs on their formulary.

219 Harriet Ryan, Lisa Girion & Scott Glover, ‘You Want a Description of Hell?’ OxyContin’s 12-Hour Problem, *LA TIMES* (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/>.

220 *Id.* The 2001 sales data was disclosed in litigation with the state of West Virginia. See *State of West Virginia ex rel., et al. v. Purdue Pharma L.P., et al.*, Civil Action No. 01-C-137-5, Circuit Court of McDowell County, West Virginia.

221 Ryan, *supra*.

969. It was not apparent from the AMCP Daily Dose email, but the study was both funded by PURDUE and co-authored by a PURDUE employee.²²² The Purdue-sponsored study purported to provide “evidence that reformulated ER oxycodone [was] associated with reductions in abuse rates” and substantial \$430 million abuse-related medical cost savings.²²³ PURDUE intended for this study, which overstates and misrepresents the effectiveness of ADF drugs to deter abuse, to reach Third Party Payors. As the study further concluded that “[p]ayers and policy-makers should consider these benefits as they devise and implement new guidelines and policies in this therapeutic area.”²²⁴

970. In September 2014, PURDUE doubled down on the misrepresentations, funding an extension of the study, which was published in Front Group AAPM’s Journal of Pain Medicine and entitled *Societal Economic Benefits Associated with an Extended-Release Opioid with Abuse-Deterrent Technology in the United States*.²²⁵ The commentary on the extension again stated, without solid evidentiary support to back it up, that “[r]eformulated ER oxycodone may reduce...abuse-related costs as well.”²²⁶ It also parroted Defendants’ mantra regarding the under treatment of pain, exaggerating the prevalence of chronic pain conditions in American adults (i.e. over 100 million suffer), and notes staggering healthcare costs of “\$560-635 billion annually.”²²⁷

971. The extension estimates indirect cost savings for the reformulation as follows: societal benefits of “\$96 million in cost savings to the criminal justice system,” “\$209 million for

²²² Rossiter, et al., *Medical cost savings associated with an extended-release opioid with crush-resistant technology in the U.S.*, 17 J. MED. ECON. 279 (Apr. 2014).

²²³ Id.

²²⁴ Id.

²²⁵ Noam Y. Kirson, et al., *Societal Economic Benefits Associated with an Extended-Release Opioid with Abuse-Deterrent Technology in the United States*, 15 J. PAIN MEDICINE 1450 (Sept. 2014), available at <https://academic.oup.com/painmedicine/article/15/9/1450/1892618>.

²²⁶ Id.

²²⁷ Id.

reductions in premature deaths,” “\$181 million for reduction in lost wages and employment,” “\$34 million for reductions in excess medically related absenteeism costs, \$15 million in reductions in excess disability costs, and \$38 million for reductions in presentation costs.”²²⁸ In addition, the study calculated annual savings of \$33 million for “excess medical and drug costs for caregivers of opioid abuse patients.”²²⁹

972. The research for both misleading studies was funded by Purdue and both publications were also co-authored by PURDUE employee Rami Ben-Joseph, Ph.D. Defendant’s misrepresentations regarding the cost savings as to reformulated opioids were calculated to reach managed care organizations and create the false sense of security, when in reality the same or greater abuse potential exists for the ADF.

2. CEPHALON’s False and Misleading Messages to Third Party Payors

973. As part of CEPHALON’s formulary access and coverage enterprise, it developed a dedicated “managed care” (also called “Regional Account Executives” or “Managed Markets”) sales group, many of whom had advanced science degrees, whose job it was to call on Third Party Payor pharmacy directors and personnel. These specialized Managed Markets representatives presented false and misleading studies/abstracts to Third Party Payors to influence placement of CEPHALON’s drugs on its formularies.

974. From the time CEPHALON launched Fentora in 2006 to replace its drug Actiq, a key focus was access on Third Party Payor formularies to secure “favorable reimbursement for a branded opioid analgesic.” The Brand Plan at the time spelled this out clearly:

²²⁸ Noam Y. Kirson, et al., *Societal Economic Benefits Associated with an Extended-Release Opioid with Abuse-Deterrent Technology in the United States*, 15 J. PAIN MEDICINE 1450 (Sept. 2014), available at <https://academic.oup.com/painmedicine/article/15/9/1450/1892618>.

²²⁹ *Id.*

Managed Care/Third-Party Payers

Many chronic pain patients remain marginalized by BTP because BTP is underrecognized and the economic and social value of rapid onset analgesia has not been established. A recent publication of BTP treatment guidelines indicates that the optimal treatment for BTP is a rapid ROO; unfortunately this will need ongoing validation and understanding with TPPs. Also, the chronic pain market is a highly genericized market. TPPs continually seek to control costs by driving utilization to generics or lower cost branded products. TPPs use tools such as tiered co-pays, prior authorization, step edits, and/or quantity limits to impact drug utilization. Therefore, it will be extremely important for Cephalon to continue to improve its relationship with TPPs in order to secure favorable reimbursement for a branded opioid analgesic. For this reason, a comprehensive managed markets plan will need to be executed in order to achieve favorable reimbursement status and access to FBT for appropriate physicians and patients.

975. The 2011 Brand Plan specifically targeted “payers” in order to “maintain current formulary status for FENTORA in the face of emerging competition in the ROO market. The primary tactic is a proposed regional targeting effort to appropriately support the reimbursement process.”

976. The 2011 Brand Plan also featured a Fentora Reimbursement Program which, in CEPHALON’s own words, “provides tools and services that may facilitate the reimbursement process.” According to CEPHALON’s website, the Fentora Reimbursement Program is designed to help patients and physicians with pre-authorizations and denied claims. In reality, however, the Fentora Reimbursement Program is a program that CEPHALON has used primarily to help physicians overturn adverse Fentora coverage decisions by payers.

977. The Fentora Reimbursement Program is provided free of cost to health care professionals, and it has been a key resource for sales representatives in their unsafe and unapproved promotions of Fentora. Without assistance, reimbursement issues may be costly to physicians in two ways. First, in the event of a denied claim for coverage, a medical practice must bill the patient for drugs already provided. Given the high cost of many oncology drugs, the patient may be unable to afford payment. If this cost is beyond the patient’s means, the practice may then be required to assume the cost itself.

978. Second, even in the event that coverage is eventually approved, the process of

obtaining that coverage can be costly for physicians and their staffs, requiring time-consuming interaction with payers. In a recent study published by the Zitter Group in September 2010, the average time required to process a typical oncology prior authorization was nearly one hour. The study further revealed that prior authorizations have a direct impact on prescribing decisions. Oncologists and practice managers reported that prior authorizations are the one payer management tool that most affects therapy utilization. Prior authorizations may be costly for patients as well, requiring them to postpone treatment until a coverage decision is reached. For all of these reasons, reimbursement concerns have been a frequent physician objection against prescribing Fentora.

979. Such objections were particularly prevalent with regard to unsafe and unapproved uses of the drug. When prescribing drugs for on-label indications, coverage denials are relatively unlikely, and the reimbursement process is simple and straightforward. However, when prescribing a drug for unapproved uses, coverage denials are increasingly likely, and the reimbursement process becomes correspondingly more time-consuming and complicated. A physician who writes a prescription for an unapproved use may be required to spend considerable time interacting with the patient's insurance payer, arguing that the particular circumstances of the patient justify coverage of the unsafe and unapproved prescription. The difficulty of arguing the physician's case increases when the alternative on-label therapy is significantly cheaper than the unapproved use. All else being equal, physicians are, understandably, inclined to prescribe the cheaper, on-label regimen rather than the more expensive, unsafe and unapproved combination in order to simplify the reimbursement process.

980. CEPHALON has been required to counter physicians' inclination not to prescribe a powerful opioid for the treatment of certain unsafe and unapproved, non-cancer breakthrough pain. Thus, CEPHALON needed a mechanism to remove the reimbursement burden from physicians' shoulders. The Fentora Reimbursement Program has accomplished this objective.

981. CEPHALON acknowledged internally that one of the biggest obstacles to growing Fentora sales is the lack of reimbursement for breakthrough pain. CEPHALON increased the size of its reimbursement support team to minimize this obstacle, spending over \$3 million per year (with nearly \$4 million budgeted for 2011) to provide customized reimbursement support services to doctors and their office managers, including a Fentora Hotline. CEPHALON performed numerous interventions on behalf of healthcare providers seeking to be reimbursed for unsafe and unapproved Fentora prescriptions.

982. When a physician or physician's office contacts CEPHALON's hotline for reimbursement support to overturn a denial for unsafe and unapproved uses, the company used a pre-populated form with all relevant data and studies it has identified supporting the use and reimbursement of Fentora for those uses. The pre-populated form allows physicians or their staff to only fill in the patient specific information and send it to the payor, requesting that the payor reimburse for such unsafe and unapproved use of Fentora. Importantly, CEPHALON has generated a pre-populated form for non-cancer breakthrough pain to aid physicians in making their case for unsafe and unapproved reimbursement.

983. CEPHALON's use of the Fentora Reimbursement Program to reverse reimbursement denials for unsafe and unapproved prescriptions of Fentora was part of its scheme to induce physicians to prescribe and utilize Fentora for unsafe and unapproved uses without concern for the time, resources or lost profits associated with addressing reimbursement issues raised by third party payors themselves.

3. JANSSEN's False and Misleading Messages to Third Party Payors

984. As part of JANSSEN's formulary access and coverage enterprise, it developed a dedicated "managed care" (also called "Regional Account Executives" or "Managed Markets") sales

group, many of whom had advanced science degrees, whose job it was to call on Third Party Payors' pharmacy directors and personnel. These specialized Managed Markets representatives presented false and misleading studies/abstracts to Third Party Payors to influence placement of Janssen's drugs on its formularies.

985. The JANSSEN Managed Markets representatives were specifically trained to initiate the Company's rehearsed false and misleading safety and efficacy messages designed to cause Third Party Payor to add JANSSEN's drugs to its formularies.

986. The Company trained sales representatives through role-playing exercises to promote its drugs based on false and misleading safety and efficacy statements that had been rejected by the FDA.

987. The JANSSEN Managed Markets representatives did as they were trained and instructed, and the JANSSEN formulary access and coverage enterprise succeeded in deceiving Plaintiff MMO into adding Janssen's drugs to its formulary.

988. JANSSEN's sales representatives were encouraged to be involved with prior authorization process with Ultram ER, Nucynta and Nucynta ER in order to evade Third Party Payor drug formulary restrictions. Prior authorization manipulation was part of their business plans. Defendants' District Managers touted that the number one sales representative in the country in 2012 got prescriptions by going to physician offices and simply flagging the charts with Ultram ER stickers and doing prior authorizations for each patient. This practice was encouraged by the Regional Business Director and other District Managers.

989. JANSSEN's sales representative involvement in the prior authorization process endangered the patients' HIPAA rights and was designed to bypass the existing formulary process to gain the prescription.

990. JANSSEN's territory business plans often included tracking of doctors by their volume of private insurance patients, average duration of treatment, and the average revenue from JANSSEN drugs. JANSSEN management utilized this private insurance volume information in order to determine which doctors to target for expensive meals and cash payment.

4. DEPOMED's False and Misleading Messages to Third Party Payors

991. As part of DEPOMED's formulary access and coverage enterprise, it developed a dedicated "managed care" (also called "Regional Account Executives" or "Managed Markets") sales group, many of whom had advanced science degrees, whose job it was to call on Third Party Payor pharmacy directors and personnel. These specialized Managed Markets representatives presented false and misleading studies/abstracts to Third Party Payors to influence placement of DEPOMED's drugs on its formularies.

992. The DEPOMED Managed Markets representatives were specifically trained to initiate the Company's rehearsed false and misleading safety and efficacy messages designed to cause Third Party Payors to add DEPOMED's drugs to its formularies.

993. For example, the DEPOMED trained representatives through role-playing exercises to promote its drugs based on false and misleading safety and efficacy statements that had been rejected by the FDA.

994. The DEPOMED Managed Markets representatives did as they were trained and instructed, and the DEPOMED formulary access and coverage enterprise succeeded in deceiving Plaintiff MMO into adding DEPOMED drugs to its formulary.

5. ENDO's False and Misleading Messages to Third Party Payors

995. As part of ENDO's formulary access and coverage enterprise, it developed a dedicated "managed care" (also called "Regional Account Executives" or "Managed Markets") sales

group, many of whom had advanced science degrees, whose job it was to call on Third Party Payors pharmacy directors and personnel. These specialized Managed Markets representatives presented false and misleading studies/abstracts to Plaintiff MMO to influence placement of ENDO's drugs on its formularies.

996. The ENDO Managed Markets representatives were specifically trained to initiate the Company's rehearsed false and misleading safety and efficacy messages designed to cause Third Party Payors to add ENDO's drugs to its formularies.

997. For example, the Company trained them through role-playing exercises to promote its drugs based on false and misleading safety and efficacy statements that had been rejected by the FDA.

998. The ENDO Managed Markets representatives did as they were trained and instructed, and the ENDO formulary access and coverage enterprise succeeded in deceiving Third Party Payors into adding ENDO's drugs to its formulary.

999. In another example, ENDO sponsored publications specifically aimed at seeking access to Third Party Payor formularies. One such article, *Pain Management*, appeared in the P&T Digest, a "Peer-Reviewed Compendium of Formulary Considerations."²³⁰ The self-described "Tool for Formulary Decision Makers" explained its utility:

The purpose of this publication is to provide P&T committees with an understanding of options for addressing patients' chronic pain. This peer-reviewed digest examines current guidelines for pain management, therapeutic approaches to care, and strategies for managing patients with various types of pain. In consolidating this information, it serves as a valuable tool for formulary committees and is an important contribution to the medical literature.

1000. Among its many misrepresentations aimed at securing formulary access, *Pain Management* stated that most specialists in pain medicine and addiction medicine agree that patients

230 *Pain Management*, 14 *P&T Digest*: 4 (Dec. 2005),

http://www.managedcaremag.com/sites/default/files/supplements/0512_PTD_pain/PTD_pain_MC.pdf.

treated with prolonged opioid therapy do not usually develop addictive disorders.²³¹ The term usually was never defined, but the presentation as a whole suggested that the rate of addiction was so low as to be immaterial.

6. MALLINCKRODT's False and Misleading Messages to Third Party Payors

1001. As part of MALLINCKRODT's formulary access and coverage enterprise, it developed a dedicated "managed care" (also called "Regional Account Executives" or "Managed Markets") sales group, many of whom had advanced science degrees, whose job it was to call on Third Party Payor pharmacy directors and personnel. These specialized Managed Markets representatives presented false and misleading studies/abstracts to Third Party Payors to influence placement of MALLINCKRODT's drugs on its formularies.

1002. The MALLINCKRODT Managed Markets representatives were specifically trained to initiate the Company's rehearsed false and misleading safety and efficacy messages designed to cause Third Party Payors to add MALLINCKRODT's drugs to its formularies.

1003. For example, the MALLINCKRODT trained representatives through role-playing exercises to promote its drugs based on false and misleading safety and efficacy statements that had been rejected by the FDA.

1004. The MALLINCKRODT Managed Markets representatives did as they were trained and instructed, and the MALLINCKRODT formulary access and coverage enterprise succeeded in deceiving Plaintiff MMO into adding MALLINCKRODT's drugs to its formulary.

7. ACTAVIS' False and Misleading Messages to Third Party Payors

1005. As part of ACTAVIS' formulary access and coverage enterprise, it developed a dedicated "managed care" (also called "Regional Account Executives" or "Managed Markets") sales

²³¹ *Id.* At 35

group, many of whom had advanced science degrees, whose job it was to call on Third Party Payor pharmacy directors and personnel. These specialized Managed Markets representatives presented false and misleading studies/abstracts to Third Party Payors to influence placement of ACTAVIS' drugs on its formularies.

1006. The ACTAVIS Managed Markets representatives were specifically trained to initiate the Company's rehearsed false and misleading safety and efficacy messages designed to cause the Third Party Payors to add ACTAVIS' drugs to its formularies.

1007. For example, the Company trained them through role-playing exercises to promote its drugs based on false and misleading safety and efficacy statements that had been rejected by the FDA.

1008. The ACTAVIS Managed Markets representatives did as they were trained and instructed, and the ACTAVIS formulary access and coverage enterprise succeeded in deceiving Third Party Payors into adding ACTAVIS' drugs to its formulary.

8. INSYS's False and Misleading Messages to Third Party Payors

1009. The lengths to which the Manufacturer Defendants would go to defraud Third Party Payors is best exemplified by INSYS. INSYS Therapeutics was co-founded in 2002 by Dr. John Kapoor, a serial pharmaceutical industry entrepreneur "known for applying aggressive marketing tactics and sharp price increases on older drugs."²³²

1010. In 2012, INSYS received U.S. Food and Drug Administration (FDA) approval for Subsys, a fentanyl sublingual spray product designed to treat breakthrough cancer pain, and the drug

²³² *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids*, Wall Street Journal (Nov. 22, 2016), available at www.wsj.com/articles/fentanyl-billionaire-comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968.

proved incredibly successful financially.²³³ INSYS had “the best-performing initial public offering in 2013,” and, over the next two years, revenues tripled and profits rose 45%.²³⁴ The value of company stock increased 296% between 2013 and 2016.²³⁵

1011. As noted in a Permanent Subcommittee on Investigations report Sen. McCaskill and Sen. Rob Portman issued on October 4, 2016, the prior authorization process “requires additional approval from an insurer or its pharmacy benefit manager before dispensing. ... Prior authorization policies can also impose ‘step therapy,’ which requires beneficiaries to first use less expensive medications before moving on to a more expensive approach.”²³⁶

1012. With regard to INSYS specifically, recent court filings explain that insurers have “required that a prior authorization be obtained before a claim [can] be submitted for a Subsys prescription.”²³⁷ This process includes “confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of those factors was not present, the prior authorization would be denied ... meaning no reimbursement would be due.”²³⁸ These screening processes reportedly raised significant obstacles to Subsys prescriptions shortly after INSYS introduced the drug.

1013. According to a criminal indictment filed against former INSYS CEO Michael Babich and five other INSYS executives, an internal company analysis in November 2012 revealed

²³³ *Id.*

²³⁴ *Id.*

²³⁵ *An Opioid Spray Showered Billionaire John Kapoor in Riches. Now He’s Feeling the Pain, Forbes* (Oct. 4, 2016) (www.forbes.com/sites/matthewherper/2016/10/04/death-kickbacks-and-a-billionaire-the-story-of-a-dangerous-opioid/).

²³⁶ *Senate Permanent Subcommittee on Investigations, Combating the Opioid Epidemic: A Review of Anti- Abuse Efforts in Medicare and Private Health Insurance Systems* (Oct. 4, 2016); see also *Department of Health and Human Services, Centers for Medicare & Medicaid Services, How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage (MA-PDs) Use Pharmacies, Formularies, & Common Coverage Rules* (Oct. 2015).

²³⁷ *Complaint* (July 12, 2017), *Blue Cross of California, Inc., et al. v. INSYS Therapeutics, Inc., D. Ariz.* (No. 2:17 CV 02286).

²³⁸ *Id.*

that insurers and PBMs approved reimbursements for Subsys in only approximately 30% of cases.²³⁹

1014. In response to these challenges, INSYS created a prior authorization unit, known at one point as the INSYS Reimbursement Center (IRC), to intervene with PBMs and secure reimbursements between January 2013 and October 2016.²⁴⁰ Led by an INSYS employee, IRC employees reportedly received significant financial incentives and management pressure - including quotas and group and individual bonuses - to boost the rate of Subsys authorizations.²⁴¹ According to a former INSYS employee, they personally pressured IRC employees to improve the rate of prescription approvals, noting that “Dr. Kapoor’s not happy, we have to get these approvals up.”²⁴²

1015. The PA Team was trained and directed to conduct various techniques to gain approval. According to one former employee, when the PBM called to ask what Subsys was being prescribed for and if the patient had tried other medications due to “step therapy” policies, the PA Team was instructed to lie about the other drugs the patient had taken; the PA Team was given the cheat sheet lists of other drugs, and they were trained to tell the PBM that the patient had taken drugs from that list, even though the patient had not taken the drugs. This former employee stated that the PA Team was “helping” the prescriber by handling all of the paperwork involved in getting prior authorization from the insurance company, paperwork that would normally have to be done by the doctor’s staff. Sometimes the insurance companies would call doctors’ offices to determine that the INSYS employee was a valid employee of the doctor’s office. According to CW6, many prescribers

²³⁹ *Indictment (Dec. 6, 2016), United States v. Babich, et al., D. Mass. (No. 1:16 CR 10343).*

²⁴⁰ *See Complaint (July 12, 2017), Blue Cross of California, Inc., et al. v. INSYS Therapeutics, Inc., D. Ariz. (No. 2:17 CV 02286).*

²⁴¹ *Murder Incorporated: INSYS Therapeutics, Part I, Southern Investigative Reporting Foundation (Dec. 3, 2015) (sirf-online.org/2015/12/03/murder-incorporated- the-INSYS-therapeutics-story/); see also Indictment (Dec. 6, 2016), United States v. Babich, et al., D. Mass. (No. 1:16 CR 10343).*

²⁴² *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids, WALL STREET JOURNAL (Nov. 22, 2016).*

had informed their staff to affirm that the INSYS employees were indeed employees of the doctor's office.

1016. This former employee also stated that the PA Team was directed to tell PBMs that a prescription had been written for a three-month supply even when the prescription specified a one-month supply.

1017. Some PBMs became suspicious that their caller IDs displayed that the PA Team member was calling from an Arizona area code but claimed to be calling from a doctor's office located in another state. When the PA Team informed CEO Babich of this problem, CEO Babich said he would arrange for the PA Team to get a phone system that would mask the outgoing phone number. On or about February 28, 2013, when the PA Team moved into new offices across the street from INSYS headquarters, a new phone system had been installed which masked their numbers from appearing on caller ID.

1018. INSYS knew that Subsys usage was primarily off-label because the PA Team was given the patient's information with the diagnosis and the list of the drugs that the patient had already taken. The majority of prescriptions were written for peripheral neuropathy caused by diabetes, lower back pain, and sciatica, in that order. Only 10% of the prescriptions reflected cancer as a diagnosis, and it was such a rare occurrence that every time the PA Team saw cancer as a patient's diagnosis, they would get "stoked."

1019. The PA Team was involved in the training of the sales representatives so that the sales representatives knew what to tell prescribers regarding which diagnoses would get authorized so that the physician did not exclude off-label use. For example, one former employee said that the sales representatives were taught to say things such as "Subsys works great on this diagnosis (like lower back pain), too." During the training then-VP of Marketing instructed the sales representatives to use

the term “breakthrough pain” instead of “breakthrough cancer pain” with health care professionals.

1020. INSYS’s 2013 “Brand Plan” specifically included strategies with which to “mitigate prior authorization barriers.”²⁴³ Some Third Party Payors (acting either directly or through their PBMs) required prior authorization for Subsys prescriptions to ensure it was prescribed for cancer patients only. In response, INSYS adopted an elaborate scheme aimed at misleading PBMs and health plans as to patients’ medical histories, successfully misleading Third Party Payors or their PBMs as to the condition for which Subsys was prescribed.²⁴⁴

1021. INSYS management was aware that only about 10% of prescriptions approved through the Prior Authorization Department were for cancer patients. An Oregon Department of Justice Investigation found that 78% of preauthorization forms submitted by INSYS on behalf of Oregon patients were for unsafe and unapproved uses. Physicians are allowed to prescribe medications for indications outside of FDA guidelines if they see fit, but it is illegal for pharmaceutical companies to market a drug for unsafe and unapproved use.

1022. The core of the INSYS scheme was outright lying in getting prior authorizations approved for Subsys. INSYS’s prior authorization unit did this by changing patients’ diagnoses to cancer. Absent the alleged changes, Third Party Payors would have never paid for the Subsys prescriptions. The result has been that Third Party Payors have approved reimbursement of prescriptions for Subsys at vastly higher rates than those of its rivals in the Fentanyl marketplace.

1023. The INSYS prior authorization unit was set up to assist patients with complex insurance paperwork. Its goal was simple: The patient signed a few forms and INSYS handled the messy paperwork. Patients would get the Subsys, prescribers would not have to scramble for an

243 U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member’s Office, *Fueling An Epidemic: INSYS Therapeutics And The Systematic Manipulation Of Prior Authorization* (Sep. 1, 2017), at Ex. A.

244 *Id.* at 2-3.

alternate medication, and INSYS would book thousands of dollars in revenue per prescription.²⁴⁵

1024. In reality what the INSYS prior authorization unit did was take advantage of PBM approvals to work a type of bureaucratic alchemy whereby a torrent of unsafe and unapproved Subsys prescriptions would be transformed into ones associated with medically urgent cancer diagnoses.

1025. Unmistakably, its prior authorization unit was the key piece in helping INSYS to double the size of the Fentanyl marketplace to more than \$500 million in less than two years. Lost in the cascade of prescriptions, however, has been the human toll from peddling Subsys like a new piece of software or an improved detergent.²⁴⁶

1026. Since Subsys was launched in January 2012, the FDA's Adverse Events Reporting System lists hundreds of deaths for which medical providers have pointed to Subsys as the probable candidate for triggering an adverse reaction.

1027. Instead of answering "yes" to questions about breakthrough cancer pain, INSYS prior authorization unit employees were to answer, "yes, they have breakthrough pain," which was both an affirmative answer but ambiguous enough to mean virtually anything.²⁴⁷

1028. Through the spring of 2014, Subsys prior authorization approval rates remained impressive, but pharmacy benefit managers began to push back, sometimes demanding to speak with the physician about the diagnosis. If the pharmacy benefit manager called the prescriber, that was a big problem in and of itself as the prior authorization unit was in no way "from" any doctor's office.²⁴⁸

1029. To reverse the trend of a slowdown in number of approvals, INSYS developed

²⁴⁵ Roddy Boyd, *Murder Incorporated: INSYS Therapeutics, Part I*, Southern Investigative Reporting Foundation, *The Investigator*, December 3, 2015, available at <http://sirf-online.org/2015/12/03/murder-incorporated-the-INSYS-therapeutics-story/>

²⁴⁶ *Id.*

²⁴⁷ *Id.*

²⁴⁸ *Id.*

what prior authorization employees called “the spiel,” a series of dialogues (to commit to memory), designed to address detailed questions about whether a patient had breakthrough pain and cancer. When someone from a pharmacy benefit management office asked about a patient’s having breakthrough pain from cancer, the INSYS prior authorization employee would reply, “The physician has stated that Subsys is approved for treating breakthrough cancer pain so (he or she) is treating breakthrough pain.” Prior authorization employees, per their instructions, would invent conversation to suggest they were right inside the prescriber’s office — something along the lines of “You should see this guy. It’s a real sad case and the doctor is upset about it.”²⁴⁹

1030. INSYS’s prior authorization unit (also known internally as the “insurance reimbursement center” or “IRC”) employees were trained and rewarded for saying anything, including purportedly inventing patient diagnoses, to get Subsys approved.²⁵⁰

1031. Materials produced by INSYS to the Senate minority staff suggest that INSYS was aware of the danger of its problematic practices towards MMO and other THIRD PARTY PAYORS. Specifically, on February 18, 2014, Compliance Implementation Services (CIS)—a healthcare consultant— issued a draft report to INSYS titled, “INSYS Call Note, Email, & IRC Verbatim Data Audit Report.”²⁵¹ The introduction to the report explained that “CIS was approached by INSYS’ legal representative ... on behalf of the Board of Directors for INSYS to request that CIS support in review of certain communications with health care professionals and INSYS employees, and report how

²⁴⁹ *Id.*

²⁵⁰ Roddy Boyd, *The Brotherhood of Thieves: INSYS Therapeutics*, Southern Investigative Reporting Foundation, *The Investigator*, January 25, 2016, available at <http://sirf-online.org/2016/01/25/the-brotherhood-of-thieves-INSYS-therapeutics-2/>

²⁵¹ U.S. Senate Homeland Security & Governmental Affairs Committee, *INSYS Therapeutics and the Systemic Manipulation of Prior Authorization* (quoting Compliance Implementation Services, *INSYS Call Note, Email & IRC Verbatim Data Audit Report* (Feb. 18, 2014) (INSYS_HSGAC_00007763)).

there were being documented.”²⁵² INSYS had expressed concerns “with respect to communications with health care professionals by INSYS employees being professional in nature and in alignment with INSYS approved topics regarding off or on-label promotion of an INSYS product, and general adherence to INSYS documentation requirements.”²⁵³ An additional concern “stemmed from the lack of monitoring of commercial activities where these types of interactions could occur.”²⁵⁴

1032. Similarly, INSYS management was urged to formally draft specific standard operating procedures “specific to each job function within the IRC [INSYS Reimbursement Center],” accompanied by “adequate training and understanding of these processes.”²⁵⁵ To ensure compliance with standards, INSYS was also directed to create an electronic system to allow management “to monitor both live and anonymously IRC employee communications both incoming and outgoing.”²⁵⁶ Finally, CIS recommended that INSYS institute a formal process for revising and updating “IRC documentation used for patient and health care professionals data.”²⁵⁷

1033. Yet within a year of this conclusion, according to a recording, an INSYS IRC employee appeared to have misled a PBM representative regarding the IRC employee’s affiliation and the diagnosis applicable to the patient. The alleged result, in that case, was death due to inappropriate and excessive Subsys prescriptions.

1034. One former INSYS sales representative described the motto of this approach to patients as “[s]tart them high and hope they don’t die.”²⁵⁸

²⁵² *Id.* at INSYS_HSGAC_00007765.

²⁵³ *Id.*

²⁵⁴ *Id.*

²⁵⁵ INSYS_HSGAC_00007771.

²⁵⁶ *Id.*

²⁵⁷ *Id.*

²⁵⁸ INSYS_HSGAC_00007772.

1035. INSYS's unlawful promotion of Subsys included the specific targeting of prescribers and Third Party Payors in Plaintiff's community. Specifically, INSYS sales representatives were directed to modify or fabricate diagnosis codes on a patient's prior authorization form in an effort to ensure payment by Third Party Payors. For example, if the patient was suffering from low back pain, the physician's office completed the prior authorization form using an appropriate pain-related diagnosis code and then sent the form along to INSYS. INSYS would then add a cancer-related diagnosis code to the patient's form before submitting the claim for payment to New York Third Party Payors. This was all done despite the fact that the physician was not an oncologist and the patient was not being treated for any cancer-related conditions. INSYS's conduct was designed to obtain payment from Third Party Payors for the unsafe and unapproved use of INSYS, irrespective of the patient's underlying medical condition.

C. Concerted Efforts of All Defendants to Suppress Evidence of Diversion

1036. A critical component of the formulary access and coverage enterprise was *all* of the Defendants' concerted efforts to illegally suppress evidence of drug diversion, which they were obligated to report. Absent this concealment, Third Party Payors would have been on notice that a significant amount of the opioid drugs for which it had paid were not prescribed for legitimate medical need, but rather made their way to the black market. This would have led Third Party Payors to employ various fraud fighting tools to thwart 'market prescribing,' and also affected its formulary access and status decisions regarding opioid drugs. It would also have revealed to Third Party Payors that representations regarding the non-addictive properties of opioid drugs were false. In short, Defendants' drug diversion concealment enterprise was a key component of Defendants' formulary access and coverage enterprise.

1037. Absent this concealment, health plans would not have made the coverage and formulary placement decisions it did with respect to opioid drugs, and would have expended far less money on the reimbursement of opioid drugs.

1038. The success of the drug diversion concealment enterprise hinged on *all actors* in the supply chain working to conceal evidence of drug diversion. Thus, in addition to the Manufacturer Defendants, the Distributor Defendants and Pharmacy Defendants were key integral players in the success of the formulary access and coverage enterprises.

XIII. Distributor Defendants Have A Duty to Report and Stop Suspicious Orders of Opioids.

1039. As noted above, Defendants' profit was not merely tied to the prescription market for opioid drugs, but also to the black market. All Defendants worked together to conceal evidence of drug diversion, ensuring the protection and expansion of the black market for opioid drugs, from which all Defendants were profiting. The drug diversion concealment enterprise was critical to the success of the formulary access and coverage enterprise (which bolstered and secured all Defendants' profits resulting from opioid drugs).

1040. The opioid supply chain begins with manufacturers (including the Manufacturer Defendants), who manufacture and package the pills. The Manufacturer Defendants then transfer the opioids to wholesale distributors (including the Distributor Defendants). Wholesale Distributors then dispense the opioids to hospitals and pharmacies. Those entities (which include the Pharmacy Defendants) then dispense drugs to patients. Each of these Defendants under federal and state law have a duty to report suspicious orders.

A. Distributor Defendants' Duties.

1041. Distributor Defendants have an affirmative duty to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs.

1042. Congress created a closed system of distribution of prescription opioids with the CSA that required all manufacturers and distributors to obtain registrations and investigate, report, and stop suspicious orders of prescription opioids.

1043. The closed loop system established by the CSA combats diversion by requiring that “all legitimate handlers of controlled substances must obtain a DEA [Drug Enforcement Administration] registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion.”²⁵⁹

1044. The CSA and its implementing regulations restrict the distribution of controlled substances by requiring drug distributors and manufacturers to monitor, identify, stop, and report suspicious orders of controlled substances, including orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.²⁶⁰

1045. The main objective is to conquer drug abuse and to control legitimate and illegitimate traffic in controlled substances; and, to prevent the diversion of drugs from legitimate to illicit channels. All drugs, such as the controlled substances at issue in this case, are classified into five schedules. All drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and the use of substances listed therein. These are subject to strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.

1046. The Distributor Defendants of Schedule II drugs-controlled substances with a

²⁵⁹ Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to CARDINAL HEALTH, Sept. 27, 2006, p. 1 (“2006 Rannazzisi Letter”) (filed in *CARDINAL HEALTH, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-51 (D.D.C.).)

²⁶⁰ See 21 U.S.C. §§ 801-971; 21 C.F.R. §§ 1300-1321.

“high potential for abuse”, are required to maintain effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels. In addition, Distributor Defendants are supplying controlled substances to pharmacies, and, as such, must “design and operate a system to disclose to the [distributor] suspicious orders of controlled substances” and, in turn, disclose those suspicious orders to the regulating entity. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

1047. The Distributor Defendants are required to register with the Drug Enforcement Administration (DEA), pursuant to the Controlled Substances Act.²⁶¹

1048. Accordingly, each of the Distributor Defendant is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances (opioids) with a duty to comply with all security requirements imposed under that statutory scheme.

1049. In evaluating a distributor’s operations, the DEA considers “(1) whether the distributor has maintained “effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels”; (2) whether the distributor has complied with applicable state and local laws; (3) whether the distributor has previously been convicted under federal or state laws for a crime related to the sale of controlled substances; (4) the distributor’s past experience with controlled substances; and (5) “such other factors as may be relevant to and consistent with the public health and safety.”²⁶²

1050. Distributors are “one of the key components of the distribution chain” and “must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances

²⁶¹ See 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100; *Masters Pharm., Inc.*, 861 F.3d at 21.

²⁶² *Masters Pharm., Inc.*, 861 F.3d at 212 (quoting 21 U.S.C. § 823(b), (e))

only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”²⁶³

1051. Federal regulations require that Distributor Defendants “shall provide effective controls and procedures to guard against theft and diversion of controlled substances.”²⁶⁴

1052. Distributor Defendants must not ship a suspicious order.²⁶⁵ The responsibility for making the decision to ship or not to ship rests with the supplier.²⁶⁶ Every registrant under the Controlled Substances Act, including Distributor Defendants, is required to notify the DEA of suspicious orders and stop such orders, thereby ensuring that prescription opioids are not diverted for illegal purposes.

1053. The implementing federal regulations provide, “[t]he registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.”²⁶⁷

1054. “Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”²⁶⁸ This criterion is disjunctive and can stand alone or together. If an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported a suspicious. Likewise, a registrant need not wait for a

²⁶³ 2006 Rannazzisi letter, p. 1.

²⁶⁴ 21 C.F.R. § 1301.71(a). See also 21 U.S.C. § 823(b).

²⁶⁵ See Prevoznik, Thomas W., “Distributor Initiative: A National Perspective,” *Deaiverison.usdoj.gov*, U.S. Dept. of Justice, Drug Enforcement Administration, 22 Oct. 2013. Web. 25 Oct. 2017.

²⁶⁶ *Id.*

²⁶⁷ 21 C.F.R. § 1301.74(b) (*emphasis added*).

²⁶⁸ 21 C.F.R. § 1301.74(b).

“normal pattern” to develop over time before determining whether a particular order is suspicious. The size of the order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant’s customer base and the patterns throughout the relevant segment of the regulated industry.²⁶⁹

1055. “Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some “due diligence” and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order.”²⁷⁰

1056. The closed system is specifically designed with checks and balances between the registrants to ensure that controlled substances are not diverted from this closed system. The goal of the closed system, through appropriate regulation of the manufacture and distribution of drugs, is to reduce the availability of drugs subject to abuse except through legitimate channels of trade and for legitimate uses.

1057. Federal law requires Distributor Defendants to comply with State and local laws.

1058. New York State’s Rules and Regulations on Controlled Substances, Part 80 requires licensees (manufacturers and distributors holding licenses for controlled substances privileges) to inform the Department of Health of the State of New York of suspicious orders when discovered by the distributor. “A licensee shall establish and operate a system to disclose to the licensee suspicious orders for controlled substances and inform the department of such suspicious

²⁶⁹ Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to CARDINAL HEALTH, Dec. 27, 2007, p. 1 (“2007 Rannazzisi Letter”) (filed in CARDINAL HEALTH, Inc. v. Holder, No. 1:12-cv-00185-RBW, Doc. 14-8 (D.D.C.).)

²⁷⁰ *Masters Pharm., Inc.*, 861 F.3d at 212–13.

orders. Suspicious orders shall include, but not be limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”²⁷¹

1059. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.”²⁷² The guidelines set forth recommended steps in the “due diligence” process, and note in particular “[i]f an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.”²⁷³

1060. The Distributor Defendants sold prescription opioids in City of Syracuse, including hydrocodone and/or oxycodone, to retailers in City of Syracuse, which Defendants knew were likely to be diverted in City of Syracuse.

1061. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

1062. Each Distributor Defendant owes a duty to investigate and refuse suspicious orders of prescription opioids.

²⁷¹ *New York State’s Rules and Regulations on Controlled Substances, Part 80.22*

²⁷² *Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* (filed in *CARDINAL HEALTH, Inc. v. Holder*, No. 12-5061, Doc. No. 1362415 (App’x B) (D.C. Cir. Mar. 7, 2012)).

²⁷³ *Id.*

1063. Each Distributor Defendant owes a duty to report suspicious orders of prescription opioids.

1064. Each Distributor Defendant owes a duty to prevent the diversion of prescription opioids into illicit markets in New York State and City of Syracuse.

1065. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and the subsequent opioid addiction crisis ravaging City of Syracuse and the damages caused thereby.

B. The ARCOS Database

1066. Pills made and distributed in the United States are tracked in a confidential DEA database called Automation of Reports and Consolidated Orders System (ARCOS).

1067. The ARCOS database “is an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level—hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions.”²⁷⁴

1068. Distributor Defendants are required to maintain records of their transactions involving controlled substances and are required to file reports of distributions of certain controlled substances to the ARCOS database.²⁷⁵

1069. ARCOS registrants must report all movement of drugs quarterly but may elect to report on a monthly basis. Yearly there are approximately 30,000,000+ transactions reported. ARCOS data is used in criminal/civil prosecutions and provides trend analysis for other agencies.

1070. Neither the DEA nor the Defendants will voluntarily disclose the ARCOS data.

²⁷⁴ “Automation of Reports and Consolidated Orders System (ARCOS),” *Dea diversion.usdoj*, U.S. Dept. of Justice , Drug Enforcement Administration. Web. 23 Sept. 2017.

²⁷⁵ See 2006 Rannazzisi letter, p. 2. See also “Automation of Reports and Consolidated Orders System (ARCOS), Questions & Answers,” *Dea diversion.usdoj.gov*. Web. 25 Oct. 2017.

1071. However, ARCOS data for West Virginia revealed that distributors and manufacturers knew of, but did not report or stop, suspicious orders of prescription opioids.

XIV. Distributor Defendants Breached Their Duties And The DEA Gets Involved.

A. The DEA Sent Letters to the Distributor Defendants.

1072. As a result of the Distributor Defendants' failure to comply with federal law, the DEA has taken a number of actions against them.

1073. On September 27, 2006, the DEA sent a letter to "every commercial entity in the United States registered with the Drug Enforcement Administration (DEA) to distribute controlled substances."²⁷⁶ The letter states that manufacturers and distributors "share responsibility for maintaining appropriate safeguards against diversion" and "given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, **even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.**"²⁷⁷ The letter advised that "DEA will use its authority to revoke and suspend registrations in appropriate cases."²⁷⁸ The letter also provides that "in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The letter further discusses that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."²⁷⁹

1074. The DEA sent another letter on December 27, 2007 to "reiterate the

²⁷⁶ 2006 Rannazzisi Letter, p. 1.

²⁷⁷ *Id.*, pg 2 (*emphasis added*).

²⁷⁸ *Id.*

²⁷⁹ *Id.*, p. 1.

responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders.”²⁸⁰

1075. This letter reminded manufacturers and distributors of their obligation to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”²⁸¹

1076. The letter stated that in terms of reporting suspicious orders:

“Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

*When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating “excessive purchases” do not comply with the requirement to report suspicious orders, even if the registrant calls such reports “suspicious order reports.”*²⁸²

1077. The 2007 letter also said that “[f]ailure to maintain effective controls against diversion is inconsistent with the public interest . . . and may result in the revocation of the registrant’s DEA Certificate of Registration.”²⁸³

1078. The 2007 letter also references the final order issued in *Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007), which “[i]n addition to discussing the obligation to

²⁸⁰ 2007 Rannazzisi Letter, p. 1.

²⁸¹ *Id.*

²⁸² *Id.*, at p. 2.

²⁸³ *Id.*, at p. 1-2

report suspicious orders when discovered” and “some criteria to use when determining whether an order is suspicious”, the order “also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.”²⁸⁴

1079. The 2007 letter also states that the Distributor Defendants “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society”. The preservation of health and safety of the people is the presumed purpose behind the federal and state legislation concerning restrictions on the use of dangerous drugs.

B. DEA Actions against the Distributor Defendants

1080. As a result of Distributor Defendants’ refusal to comply with their legal obligations, the DEA has repeatedly taken administrative action to force compliance. The U.S. Department of Justice, Office of the Inspector General, Evaluation and Inspections Division, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.²⁸⁵ “The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.”²⁸⁶ The public records reveal many actions taken against the Distributor Defendants as set forth below.

1081. In 2007, the DEA suspended AMERISOURCEBERGEN’s license to distribute from an Orlando facility, alleging that the distribution center “had inadequate controls against

²⁸⁴ *Id.*, at p. 2.

²⁸⁵ “The Drug Enforcement Administration’s Adjudication of Registrant Actions,” *Oig.justice.gov, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003, p. 6 (May 2014). Web. 25 Oct. 2017.*

²⁸⁶ *Id.*

diversion of controlled substances by retail internet pharmacies.”²⁸⁷ In June of 2007, AMERISOURCEBERGEN entered into a settlement which resulted in the suspension of its DEA registration.

1082. In 2012, AMERISOURCEBERGEN received subpoenas from United States’ prosecutors and the DEA requesting “documents concerning a program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific, and industrial purposes.”²⁸⁸

1083. In 2008, MCKESSON agreed to pay more than \$13 million to settle DEA claims that it failed to report hundreds of suspicious orders from internet pharmacies that sold drugs online to customers who did not have legal prescriptions.²⁸⁹

1084. As DEA Acting Administrator Michele M. Leonhart publicly stated in 2008, “[b]y failing to report suspicious orders for controlled substances that it received from rogue Internet pharmacies, the McKesson Corporation fueled the explosive prescription drug abuse problem we have in this country.”²⁹⁰

1085. In 2008, MCKESSON entered into a Settlement Agreement with the DOJ and an Administrative Memorandum of Agreement with the DEA requiring that MCKESSON “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 CFR § 1301.74(b), and follow the procedures established by

²⁸⁷ Reuters Staff, “Amerisource says US DEA OKs Controlled Drug Permit,” Reuters, 27 Aug. 2007. Web. 16, Sept. 2017.

²⁸⁸ Reuters Staff, “US Seeks Info on Drug Diversion from Amerisource Bergen,” Reuters, 9 Aug. 2012. Web. 2, Oct. 2017.

²⁸⁹ See Press Release, “McKesson Corporation Agrees to Pay More than \$13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications,” U.S. Dept. of Justice, 2 May 2008. Web. 2 Oct. 2017.

²⁹⁰ *Id.*

its Controlled Substance Monitoring Program.²⁹¹

1086. As a result of these agreements, “McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA.”²⁹²

1087. Despite these prior penalties, MCKESSON’s pattern of failing to report suspicious orders continued for many years.

1088. From 2008 until 2013, MCKESSON “supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills, frequently misused products that are part of the current opioid epidemic.”²⁹³ “[E]ven after designing a compliance program after the 2008 settlement, MCKESSON did not fully implement or adhere to its own program.”²⁹⁴

1089. In January 2017, the DOJ announced that MCKESSON had agreed to pay a record \$150 million civil penalty fine for violation of the 2008 Administrative Memorandum of Agreement and suspended the sale of controlled substances from distribution centers in Colorado, Ohio, Michigan, and Florida.²⁹⁵ While the fine set a record for drug distributors, it is only about \$50 million more than the compensation last year for MCKESSON’s board chairman and chief executive John H. Hammergren, the nation’s third-highest-paid chief executive.²⁹⁶ MCKESSON has 76,000 employees and revenue of almost \$200 billion a year about the same as ExxonMobil.²⁹⁷

1090. In an Administrative Memorandum of Agreement entered into between MCKESSON, DOJ, and the DEA in 2017, the DOJ and DEA recognized, for example:

²⁹¹ 2017 McKesson Administrative Memorandum of Agreement, p. 3, Justice.gov, U.S. Dept. of Justice. Web. 25 Oct. 2017.

²⁹² *Id.*

²⁹³ Press Release, “McKesson Agrees to Pay Record \$150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs,” U.S. Dept. of Justice Office of Public Affairs, 17 Jan. 2017. Web. 9 Oct. 2017.

²⁹⁴ *Id.*

²⁹⁵ *Id.*

²⁹⁶ ‘We feel like our system was hijacked’: DEA agents say a huge opioid case ended in a whimper”, Lenny Bernstein and Scott Higman, *The Washington Post*, December 17, 2017.

²⁹⁷ *Id.*

- “McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations at McKesson Distribution Centers....”,²⁹⁸
- “McKesson failed to properly monitor its sales of controlled substances and/or report suspicious order to the DEA, in accordance with McKesson’s obligations under the 2008 Agreements, the CSA, and 21 C.F.R. §1301.74(b);”²⁹⁹
- “McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CMSP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CMSP;”³⁰⁰
- “McKesson failed to inform the DEA Field Offices and/or DEA Headquarters of suspicious orders of controlled substances made by its customers . . . including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. §1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;”³⁰¹
- “McKesson failed to report suspicious orders for controlled substances in accordance with the standards identified and outlined in the DEA Letters;”³⁰²
- “The McKesson Distribution Centers distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the course of their professional practice, as required by 21 C.F.R. § 1306.04(a).”³⁰³

1091. MCKESSON acknowledged in the 2017 settlement that “at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain

²⁹⁸ 2017 McKesson Administrative Memorandum of Agreement, p. 3, Justice.gov, U.S. Dept. of Justice. Web. 25 Oct. 2017.

²⁹⁹ *Id.* At p. 4.

³⁰⁰ *Id.*

³⁰¹ *Id.*

³⁰² *Id.*

³⁰³ *Id.*

pharmacies which should have been detected by MCKESSON as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. §1301.74(b) and 21 U.S.C. § 842(a)(5).”³⁰⁴

1092. MCKESSON also acknowledged in the 2017 settlement that “at various times during the Covered Time Period, [MCKESSON] did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by MCKESSON as suspicious in a manner fully consistent with the requirements set forth in the 2008 MOA.”³⁰⁵

1093. In November of 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against CARDINAL HEALTH Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone.

1094. In December of 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against CARDINAL HEALTH Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone.

1095. In December of 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against CARDINAL HEALTH Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone.

1096. In January of 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against CARDINAL HEALTH Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone.

1097. In 2008, CARDINAL HEALTH agreed to pay \$34 million to settle claims that it

³⁰⁴ *Id.* at p. 5.

³⁰⁵ *Id.*

failed to report suspicious sales of abused controlled substances.³⁰⁶ As stated in the DOJ's 2008 Press Release, "CARDINAL's conduct allowed the "diversion" of millions of dosage units of hydrocodone from legitimate to non-legitimate channels. **"DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances and, more specifically, to 'design and operate a system to disclose to the registrant suspicious orders of controlled substances.'** Registrants are required to inform DEA of suspicious orders upon discovery."³⁰⁷

1098. DEA Acting Administrator, Michele M. Leonhart, stated at the time:

*"Despite DEA's repeated attempts to educate CARDINAL HEALTH on diversion awareness and prevention, CARDINAL engaged in a pattern of failing to report blatantly suspicious orders for controlled substances filled by its distribution facilities located throughout the United States," . . . "CARDINAL's negligent conduct contributed to our nation's serious pharmaceutical abuse problem. This substantial civil penalty underscores DEA's determination to prevent pharmaceutical diversion and protect the public health and safety by continuing to hold companies responsible if they fail to fulfill their obligations under the Controlled Substance Act."*³⁰⁸

1099. CARDINAL HEALTH entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA as well. The 2008 MOA required CARDINAL HEALTH "to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the Controlled Substances Act and applicable DEA regulations."³⁰⁹ This document referenced allegations by the DEA that CARDINAL HEALTH failed to maintain effective controls against the diversion of controlled substances at its Auburn Facility, Lakeland Facility, Swedesboro

³⁰⁶ Press Release, "CARDINAL HEALTH Inc., Agrees to Pay \$34 Million to Settle Claims that it failed to Report Suspicious Sales of Widely-Abused Controlled Substances," The Colorado Attorney's Office, 2 Oct. 2008. Web. 2 Oct. 2017.

³⁰⁷ *Id.* (emphasis original).

³⁰⁸ *Id.*

³⁰⁹ Press Release, "DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility," Drug Enforcement Administration, 15 May 2012. Web. 16 Sept. 2017.

Facility and Stafford Facility, as well as its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”), and Denver, Colorado (“Denver Facility”).

1100. In February of 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against CARDINAL HEALTH Lakeland Facility for failure to maintain effective controls against diversion of oxycodone.

1101. In 2012, CARDINAL HEALTH reached a settlement with the DEA to resolve allegations that their Florida distribution center “failed to maintain effective controls against the diversion of controlled substances, specifically oxycodone.”³¹⁰

1102. CARDINAL HEALTH entered in an Administrative Memorandum of Agreement with the DOJ and DEA (the “2012 MOA”), which noted that “[o]n February 2, 2012, the DEA, by its Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to CARDINAL Lakeland.”³¹¹ The Order to Show Cause alleged:

- a. “Despite the 2008 MOA, CARDINAL Lakeland failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of CARDINAL;
- b. CARDINAL Lakeland failed to report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b); and
- c. CARDINAL Lakeland failed to conduct meaningful due diligence of its retail pharmacies, including its retail chain pharmacy customers to ensure that controlled substances were not diverted into other than legitimate channels.”³¹²

1103. In the 2012 MOA, CARDINAL HEALTH agreed “to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA

³¹⁰ *Id.*

³¹¹ 2012 CARDINAL HEALTH Administrative Memorandum of Agreement, p. 1.

³¹² *Id.*

and applicable DEA regulations” and CARDINAL HEALTH “shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b).”³¹³

1104. In 2016, CARDINAL HEALTH agreed to pay \$44 million in fines to resolve allegations “that it violated the Controlled Substances Act (CSA) in Maryland, Florida and New York by failing to report suspicious orders of controlled substances to pharmacies located in those states.”³¹⁴

1105. The opioid epidemic is on-going because the fines imposed by the DEA against the Distributor Defendant do not change the conduct of the wholesale distributor industry. They pay fines as a cost of doing business in an industry which generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility. And, as noted by CARDINAL HEALTH in its pleadings in *CARDINAL HEALTH, Inc. v. Holder*, 846 F. Supp. 2d 210 (D.D.C. 2012), “*suspension ... will not address the harm DEA alleges because it will not prevent pharmacies from filling illegitimate prescriptions from simply obtaining controlled substances from another distributor.*”

C. Distributor Defendants Misled the Public Concerning their Duties and Compliance

1106. In *Masters Pharmaceutical, Inc. v. U.S. Drug Enforcement Administration* (D.C. Cir., April 4, 2016), the Healthcare Distribution Management Association (HDMA), a trade association run by the Distributor Defendants, and National Association of Chain Drug Stores (NACDS) submitted briefs regarding the legal duty of wholesale distributors.³¹⁵ Inaccurately denying

³¹³ *Id.* at 3-4.

³¹⁴ Press Release, “CARDINAL HEALTH Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act,” U.S. Dept. of Justice, The U.S. Attorney’s Office, District of Maryland, 23 Dec. 2016. Web. 23 Sept. 2017.

³¹⁵ The Healthcare Distribution Management Association (HDMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors whose membership includes, among others: AMERISOURCEBERGEN Drug Corporation,

the legal duties that Distributor Defendants have failed to fulfill, they argued that:

- The Associations complained that the “DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”³¹⁶
- The Associations argued that, “DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. 80 Fed. Reg. at 55,421, 55,475-77, 55,479. Such a change in agency position must be accompanied by an acknowledgement of the change and a reasoned explanation for it. In other words, an agency must “display awareness that it is changing position” and “show that that there are good reasons for the new policy.” *Fox Television Stations, Inc.*, 556 U.S. at 515. This is especially important here, because imposing intrusive obligations on distributors threatens to disrupt patient access to needed prescription medications.”³¹⁷
- The Associations alleged “Section 1301.71 by its terms restricts DEA’s authority to delineate the requirements for “effective controls”—stating that, in evaluating a control system, the Administrator “shall use the security requirements set forth in §§ 1301.72-1301.76.” 21 C.F.R. § 1301.71(a) (emphasis added). Nothing in Sections 1301.72-1301.76 requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”³¹⁸
- The Associations complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”³¹⁹

CARDINAL HEALTH, Inc., and McKesson Corporation. See generally HDA, About, <https://www.healthcaredistribution.org/about>. Web. 6 Oct. 2017. The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. See generally NACDS, Mission, <https://www.nacds.org/about/mission/>. Web. 6 Oct. 2017.

316 Brief for HDMA and NACDS filed in *Masters Pharm., Inc. v. Drug Enf’t Admin.*, USCA Case #15-1335, Doc. No. 1607110, pp. 4–5 (D.C. Cir. Apr. 4, 2016).

317 *Id.*, at p. 8

318 *Id.*, at p.14

319 *Id.*, at p.22

- The Associations alleged (inaccurately) that “DEA’s regulations had sensibly imposed a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”³²⁰
- Also, inaccurately, the Associations argued that, “[i]mposing a duty on distributors—which lack the patient information and the necessary medical expertise—to investigate and halt orders may force distributors to take a shot- in-the-dark approach to complying with DEA’s demands.”³²¹

1107. Rejecting the Associations’ contentions, the United States Court of Appeals for the District of Columbia issued an opinion stating that “[o]nce a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some “due diligence” and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement).”³²²

1108. The Distributor Defendants have also undertaken to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

1109. For example, a CARDINAL HEALTH executive said the company “*deploys ‘advanced analytics, technology, and teams of anti-diversion specialists and investigators who are embedded in our supply chain. This ensures that we are as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.’*”³²³

1110. Given the sales volumes and the company’s history of violations, this executive was either not telling the truth, or CARDINAL HEALTH had such a system, but it ignored the

³²⁰ *Id.* At 24-25.

³²¹ *Id.* At 26.

³²² *Masters Pharm., Inc.*, 861 F.3d at 212–13.

³²³ Bernstein, Lenny et al., “How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: ‘No one was doing their job,’” *The Washington Post*, 22 Oct. 2016. Web. 6 Oct. 2017.

results.

1111. Similarly, MCKESSON publicly stated that it has “*put significant resources towards building a best-in-class controlled substance monitoring program to help identify suspicious orders and prevent prescription drug diversion in the supply chain,*” and “[o]ur team is deeply passionate about curbing the opioid epidemic in our country.”³²⁴

1112. Given MCKESSON’s past conduct, this statement is either false, or the company ignored the results of its monitoring program.

1113. Rather than abide by their duties, the Distributor Defendants and their association, the Healthcare Distribution Alliance, pressured the U.S. Department of Justice to “halt” prosecutions and spent \$13 million to lobby House and Senate members and their staff in favor of legislation called “Ensuring Patient Access and Effective Drug Enforcement Act” which, as one article described, “raises the standard for the diversion office to obtain an immediate suspension order. Now the DEA must show an “immediate” rather than an “imminent” threat to the public, a nearly impossible burden to meet against distributors, according to former DEA supervisors and other critics. They said the new law gives the industry something it has desperately sought: protection from having its drugs locked up with little notice.”³²⁵ After an explosive media report on the Distributor Defendants’ lobbying effort, the Congressman who sponsored the bill and who was slated to be the President’s new Drug Czar, withdrew his name from consideration.³²⁶

1114. Defendants spread their false and deceptive statements by marketing their branded

324 Higham, Scott et al., “Drug Industry Hired Dozens of Officials from the DEA as the Agency tried to Curb Opioid Abuse,” *The Washington Post*, 22 Dec. 2016. Web. 6 Oct. 2017.

325 Bernstein, Lenny et al., “Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control,” *The Washington Post*, 22 Oct. 2016. Web. 6 Oct. 2017.

326 Chappell, Bill, “Tom Marino, Trump’s Pick As Drug Czar, Withdraws After Damaging Opioid Report,” *NPR.Org*, 17 Oct. 2017. Web. 25 Oct. 2017.

opioids directly to physicians and their patients nationally and in City of Syracuse. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain nationally and in City of Syracuse.

1115. Defendants' direct marketing of opioids includes conducting and continuing to conduct advertising campaigns that push the supposed benefits of their branded drugs. In 2011, Defendants spent more than \$14 million on medical journal advertising of opioids, which is nearly triple of what they spent in 2001. This amount included \$8.3 million by PURDUE, \$4.9 million by JANSSEN, and \$1.1 million by ENDO. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain; and have expressly and impliedly misled and misrepresented that their drug would provide long-term pain-relief and functional improvement.

1116. Defendants' direct marketing of opioids includes promoting and continuing to promote the use of opioids for chronic pain through sales representatives, also known as "Detailers" who visit individual doctors and medical staff in their offices or conduct small-group speaker programs. To date, Defendants have not corrected this misinformation. Instead, each Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing brand opioids to physicians, which is twice as much as they spent on this practice in 2000. The amount includes \$108 million spent by PURDUE, \$34 million by Jansen, \$13 million by CEPHALON, \$10 million by ENDO and \$2 million by ACTAVIS. Defendants' detailers have been reprimanded for their deceptive promotions, including, by organizations such as the FDA.

1117. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts giving rise to the

claims that City of Syracuse now assert.

1118. In September 2017, 41 state Attorneys General served opioid manufacturers and distributors with subpoenas and document requests seeking information concerning how the companies marketed and distributed opioids.³²⁷

1119. Meanwhile, the opioid epidemic ravages New York State and City of Syracuse because the fines and suspensions imposed by the DEA did not change the conduct of Distributor Defendants. The Distributor Defendants simply pay fines as a cost of doing business in their industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

1120. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement, and allowed diversion in New York State and City of Syracuse for their economic benefit.

D. Distributor Defendants Breached their Duties

1121. “Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances . . . from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system created by the CSA collapses.”³²⁸

1122. The sheer volume of prescription opioids distributed to pharmacies in City of Syracuse and/or to pharmacies from which the Distributor Defendants knew the opioids were likely

³²⁷ Press Release, “A.G. Schneiderman, Bipartisan Coalition Of AGs Expand Multistate Investigation Into Opioid Crisis,” New York State Office of the Attorney General, 19 Sept. 2017. Web. 6 Oct. 2017.

³²⁸ Declaration of Joseph Rannazzisi, ¶ 10 (filed in *CARDINAL HEALTH, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-2 (D.D.C. February 10, 2012)).

to be diverted into City of Syracuse, is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.

1123. The Distributor Defendants failed to report suspicious orders originating from City of Syracuse or which the Distributor Defendants knew were likely to be diverted to City of Syracuse, to the federal and state authorities, including the DEA and the New York State Department of Health.

1124. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in City of Syracuse, and/or orders which Defendants knew or should have known were likely to be delivered and/or diverted into City of Syracuse.

1125. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opioids originating from City of Syracuse, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to City of Syracuse.

1126. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opioids into other than legitimate medical, scientific, and industrial channels.

1127. The Distributor Defendants breached their duty to design and operate a system to disclose suspicious orders of controlled substances and failed to inform state and federal authorities of suspicious orders when discovered, in violation of their duties under federal and state law.

1128. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.

1129. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants violated the duties imposed by federal and state law.

1130. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and their actions had and continue to have a great probability of causing substantial harm.

1131. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

XV. The Manufacturer Defendants also Failed to Prevent Diversion and Monitor, Report, and Stop Suspicious Orders.

1132. Federal and state laws imposed the same duties on the Manufacturer Defendants as the Distributor Defendants to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids.

1133. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances, like prescription opioids.³²⁹

A requirement of such registration is the:

maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial

³²⁹ See 21 U.S.C. § 823(a).

purposes.³³⁰

1134. As registrants under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.³³¹

1135. Like the Distributor Defendants, pursuant to New York State's Rules and Regulations on Controlled Substances, the Manufacturer Defendants "...shall establish and operate a system to disclose to the licensee suspicious orders for controlled substances and inform the department of such suspicious orders. Suspicious orders shall include, but not be limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."³³²

1136. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants paid "chargebacks" to the Distributor Defendants. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to

³³⁰ 21 U.S.C. § 823(a)(1).

³³¹ 21 C.F.R. § 1301.74(b). See also 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).")

³³² New York State's Rules and Regulations on Controlled Substances, Part 80.22

which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the Distributor Defendants.

1137. Federal and state laws and regulations are clear: just like the Distributor Defendants, the Manufacturer Defendants are required to “design and operate a system to disclose . . . suspicious orders of controlled substances” and to maintain “effective controls against diversion.”³³³

1138. In 2017, the DOJ fined Defendant MALLINCKRODT \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.³³⁴ As described by the DOJ:

*The government alleged that MALLINCKRODT failed to design and implement an effective system to detect and report “suspicious orders” for controlled substances – orders that are unusual in their frequency, size, or other patterns. From 2008 until 2011, the U.S. alleged, MALLINCKRODT supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders. Through its investigation, the government learned that manufacturers of pharmaceuticals offer discounts, known as “chargebacks,” based on sales to certain downstream customers. Distributors provide information on the downstream customer purchases to obtain the discount. The groundbreaking nature of the settlement involves requiring a manufacturer to utilize chargeback and similar data to monitor and report to DEA suspicious sales of its oxycodone at the next level in the supply chain, typically sales from distributors to independent and small chain pharmacy and pain clinic customers.*³³⁵

1139. The Memorandum of Agreement entered into by MALLINCKRODT in 2017 confirms that “[a]s a registrant under the CSA, MALLINCKRODT had a responsibility to maintain

³³³ 21 C.F.R. § 1301.74; 21 U.S.C. § 823(a)(1).

³³⁴ Press Release, “MALLINCKRODT Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations,” U.S. Dept. of Justice, 11 July 2017. Web. 16 Sept. 2017.

³³⁵ *Id.* (emphasis added).

effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA.”³³⁶

1140. The 2017 Memorandum of Agreement further details the DEA’s allegations regarding MALLINCKRODT’s failures to fulfill its legal duties as an opioid manufacturer to prevent diversion:

a. With respect to its distribution of oxycodone and hydrocodone products, MALLINCKRODT’s alleged failure to distribute these controlled substances in a manner authorized by its registration and MALLINCKRODT’s alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. §1301.74(b). The above includes, but is not limited to MALLINCKRODT’s alleged failure to:

- i. conduct adequate due diligence of its customers;
- ii. detect and report to the DEA orders of unusual size and frequency;
- iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
 1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
 2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and
 3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which MALLINCKRODT was aware;

- iv. use "chargeback" information from its distributors to evaluate

³³⁶ Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and MALLINCKRODT, plc. and its subsidiary MALLINCKRODT, LLC, Justice.gov, U.S. Dept. of Justice, July 2017, p. 1. Web. 25 Oct. 2017.

suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing MALLINCKRODT with data on buying patterns for MALLINCKRODT products; and

v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of MALLINCKRODT product by those downstream customers.³³⁷

1141. Defendant MALLINCKRODT agreed that “certain aspects of MALLINCKRODT’s system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007.”³³⁸

1142. Defendant MALLINCKRODT further agreed that:

*MALLINCKRODT acknowledges and agrees that the obligations undertaken in this Program do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances. MALLINCKRODT recognizes the importance of the prevention of diversion of the controlled substances they manufacture. MALLINCKRODT will design and operate a system that meets the requirements of 21 CFR 1301.74(b). MALLINCKRODT's suspicious order system will be designed to utilize all available transaction information to identify suspicious orders of any MALLINCKRODT product. Further, MALLINCKRODT agrees to notify DEA of any diversion and/or suspicious circumstances involving any MALLINCKRODT controlled substances that MALLINCKRODT discovers.*³³⁹

1143. The 2017 Agreement also contained the following:

Chargeback Data Monitoring. As part of their business model MALLINCKRODT collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to "downstream" registrants. MALLINCKRODT receives this type of data only after it is submitted to MALLINCKRODT by the direct customer, which is after the controlled substance has already been distributed. MALLINCKRODT will

³³⁷ *Id.* At pp. 2-3

³³⁸ *Id.* at p. 4.

³³⁹ *Id.*

*report to the DEA when MALLINCKRODT concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.*³⁴⁰

1144. The same business practices utilized by MALLINCKRODT regarding “charge backs” and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among the Manufacturer and Distributor Defendants.

1145. Through the charge back data, the Manufacturer Defendants could monitor suspicious orders of opioids.

1146. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

1147. The Manufacturer Defendants’ failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

1148. The Manufacturer Defendants have misrepresented their compliance with federal law.

1149. The wrongful actions and omissions of the Manufacturer Defendants have caused the diversion of opioids and have been a substantial contributing factor to and proximate cause of the opioid crisis ravaging City of Syracuse.

1150. The Manufacturer Defendants’ actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into City of Syracuse.

XVI. Defendants’ Conduct and Breaches of Duties Caused the Plaintiff Harm.

1151. As the Manufacturer Defendants’ efforts to expand the market for opioids increased so have the rates of prescription and sale of their products—and the rates of opioid related

³⁴⁰ *Id.* At p. 5.

substance abuse, hospitalization, and death among the people of the State of New York and the City of Syracuse. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into New York State and the City of Syracuse, fueling the opioid epidemic.

1152. There is “a parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.”³⁴¹

1153. “[O]pioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.”³⁴²

1154. The epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”³⁴³

1155. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.³⁴⁴

1156. The opioid epidemic has escalated in the City of Syracuse with devastating effects. Substantial opioid-related substance abuse, hospitalization and death mirrors Defendants’ increased distribution of opioids in this community.

1157. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution of opioids to City of Syracuse and areas from which such opioids are being diverted into the City of Syracuse has

³⁴¹ See Dart, Richard C. et al., “Trends in Opioid Analgesic Abuse and Mortality in the United States,” *New Engl. J. Med.* 2015; 372:241-248 (Jan. 15, 2015).

³⁴² Volkow, Nora D. et al., “Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies,” *New Engl. J. Med.* 2016; 374:1253-1263 (Mar. 31, 2016).

³⁴³ See Califf, Robert M. et al., “A Proactive Response to Prescription Opioid Abuse,” *New Engl. J. Med.* 2016; 374:1480-1485 (Apr. 14, 2016).

³⁴⁴ See Press Release, “Prescription Painkiller Overdoses at Epidemic Levels,” U.S. Dep. of Health and Human Services, Centers for Disease Control and Prevention, 1 Nov. 2011. Web. 6 Oct. 2017.

resulted in the Defendants-caused opioid epidemic to include heroin addiction, abuse, and death.

1158. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in New York State and in the City of Syracuse.

1159. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in New York State and in the City of Syracuse.

1160. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes into the City of Syracuse.

1161. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in New York State and the City of Syracuse. This diversion and the epidemic are direct causes of foreseeable harms suffered by the Plaintiff. Defendants' intentional and unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages to Plaintiff for which Plaintiff is entitled to means to abate the ongoing epidemic created by Defendants' wrongful and unlawful conduct.

1162. Plaintiff's economic damages include reimbursement for the costs associated with past efforts to eliminate, control, and deal with the hazards to public health and safety.

1163. Plaintiff's abatement damages include the costs to permanently eliminate the hazards to public health and safety and abate the ongoing public nuisance.

1164. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."³⁴⁵

³⁴⁵ See Rudd, Rose A. et al., "Increases in Drug and Opioid-Involved Overdose Deaths— United States, 2010–2015,"

1165. “A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.”³⁴⁶

1166. These community-based problems require community-based solutions that have been limited by “budgetary constraints at the state and Federal levels.”³⁴⁷

1167. Defendants’ breach of their duties caused the skyrocketing in opioid addiction in the City of Syracuse - an epidemic that threatens the safety and wellbeing of the City of Syracuse and places added strain on the capacity of local public safety agencies and emergency medical departments. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opioids, Defendants are responsible for the financial burdens their conduct has inflicted upon the Plaintiff.

XVII. Defendants’ Opioid Marketing and Diversion in New York State and City of Syracuse

1168. Defendants’ misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Indeed, patients often report that they were not warned about the risks of becoming addicted to the opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.³⁴⁸

MMWR Morb. Mortal Wkly. Rep. 2016 Dec 30; 65(5051):1445-1452.

346 “The Prescription Opioid Epidemic: An Evidence-Based Approach,” Johns Hopkins Bloomberg School of Public Health, p. 9 (Nov. 2015).

347 See “Epidemic: Responding to America’s Prescription Drug Abuse Crisis,” Executive Office of the President of the United States, p. 1 (2011).

348 Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), <https://www.prnewswire.com/news-releases/missed-questions-missed-opportunities-300210666.html>.

A. The Results Of Defendants' Wrongful Conduct On New York And City of Syracuse

1. New York and City of Syracuse are Flooded with Prescription Opioids as a Result of Defendants' Conduct.

1169. Defendants' deceptive marketing scheme caused and continues to cause doctors nationwide, in New York State, and in the City of Syracuse to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

1170. Orthopedic surgeon, Andrew Wickline, with Genesee Orthopedics, in Central New York, stated that he used to prescribe 100 narcotic pain pills for patients undergoing surgery with a refill after three weeks, but that was ten years ago.³⁴⁹ Whereas, now he prescribes 30 pain pills with rare refills.³⁵⁰ Dr. Wickline blames “kindly administrators and whoever came up with the happy/sad face chart to describe pain”.³⁵¹ According to Dr. Wickline, “[n]on-physician health care administrators decided that pain is the fifth vital sign (in the 90s), ... [s]o their idea was that patients shouldn't be in pain and, in fact, if the patient is in pain, it's the doctor's fault and the doctor is liable for that. So, it became a sudden thing that we needed to manage.”³⁵²

349 “How prescription drugs started opioid epidemic”, by Amy Neff Roth, *Times Telegram*, May 17, 2017.

350 *Id.*

351 *Id.*

352 *Id.*

1990

American Pain Foundation
recommended to make
pain “the fifth vital sign” ³⁵³

2001

**The Joint Commission launched
Pain: The Fifth Vital Sign
campaign.** ³⁵⁴

2004

Federation of State Medical Boards
called on state medical boards to make
under treatment of pain punishable. ³⁵⁵

1171. Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to \$288 million.

1172. Since that time, Defendants have continued to spend enormous amounts of money to infiltrate and influence the New York State and City of Syracuse markets, including

³⁵³ *Opioid and Heroin Epidemic, Our Problem, Our Solutions, A Community Forum, presented by the Onondaga County Drug Task Force*, <http://www.ongov.net/health/opioids/documents/HeroinForumSlides.pdf>

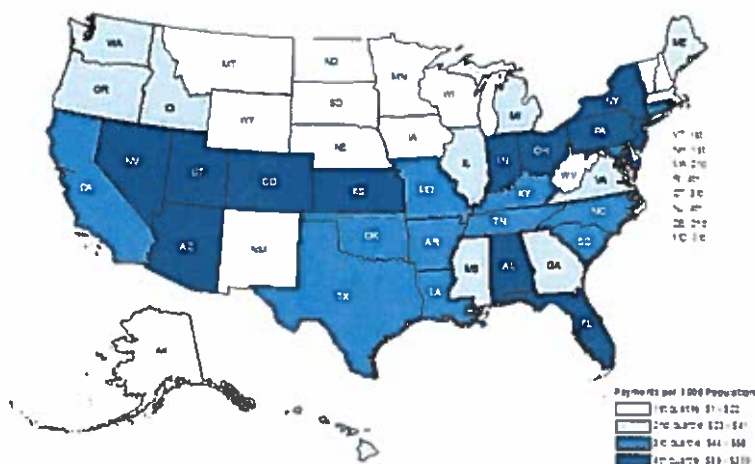
³⁵⁴ *Id.*

³⁵⁵ *Id.*

paying New York State physicians for speaking engagements and other means of promoting their opioid drugs.³⁵⁶

1173. In a first-of-its-kind study, Boston Medical Center researchers found that 1 in 12 doctors have received money from drug companies marketing prescription opioid medications.³⁵⁷ The researchers found that from 2013 to 2015, doctors received more than \$46 million in payments from drug companies pushing opioids. About two-thirds of the payments came from speaking fees.

1174. New York had recorded some of the most payments to doctors in drug companies prescribing opioids:



1175. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the United States.

1176. The National Institute on Drug Abuse ("NIDA"), a component of the National Institutes of Health ("NIH"), has identified several factors that have contributed to the nation's prescription opioid epidemic, including drastic increases in the number of prescriptions written and

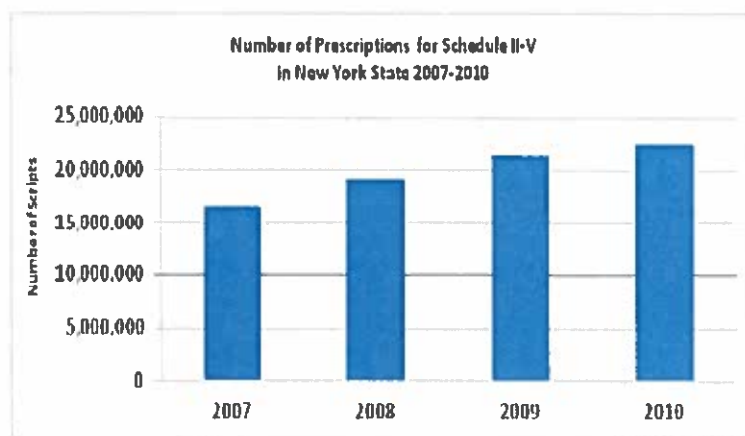
³⁵⁶ See "Dollars for Docs," <https://projects.propublica.org/docdollars/>, ProPublica. Web 13 Oct. 2017.

³⁵⁷ Hadland, S.E. et al., "Industry Payments to Physicians for Opioid Products, 2013-2015," 2017 Sep; 107 (9): 1493-1459.

dispensed, greater social acceptability for using medications for different purposes, and aggressive marketing by the pharmaceutical companies.³⁵⁸

1177. Pharmaceutical company representatives began making frequent trips to New York State in the late 1990s to promote new opioid painkillers – including PURDUE’s Oxycontin.

1178. In New York, the number of prescriptions for all narcotic painkillers increased from 16.6 million in 2007 to nearly 22.5 million prescriptions in 2010.³⁵⁹



Data Source: NYS DOH, Bureau of Narcotics Enforcement

1179. In 2012, New York State had between 52-71 opioid prescriptions per 100 people.³⁶⁰

According to the US Department of Justice, “Oxycodone distribution peaked in 2012 in New York while 2016 values remained more than 50% higher than in 2006 and seven-fold higher than in 2000.”³⁶¹

1180. The *Buffalo News* published a series of stories about the impact of prescription

³⁵⁸ See 2014 Congressional testimony presented by NIDA Director Nora Volkow, MD, <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress>

³⁵⁹ NYS Department of Health, Bureau of Narcotics Enforcement

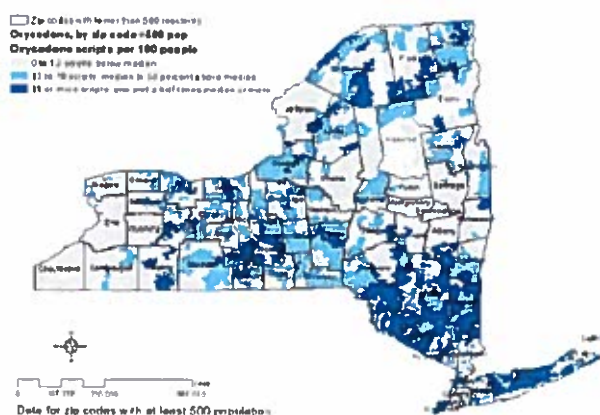
³⁶⁰ “Vital Signs: Opioid Painkiller Prescribing infographic,” Centers for Disease Control and Prevention, available at <https://www.cdc.gov/vitalsigns/opioid-prescribing/infographic.html>, (citing IMS, National Prescription Audit, 2012).

³⁶¹ New York State Association of Counties, et al., “New York State Opioids Info Book,” Sept. 2017, p. 13, (citing US Department of Justice, available at <http://www.deadiversion.usdoj.gov/acros/index.html>).

drug abuse and misuse throughout New York. The series found that doctor shopping, the use of multiple painkiller prescriptions and easy access to opioids have created a “perfect storm”, not only in the western part of the state, but throughout New York.³⁶²

1181. “Maps 1 and 2 depict the geographic distribution of the two drugs. Hydrocodone use appears concentrated in the western and central parts of the state, while oxycodone use was prevalent in the south-eastern part of the state and Long Island.”³⁶³

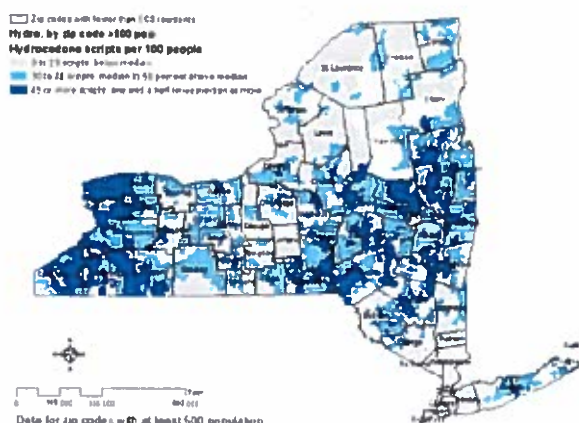
Map 1 – Oxycodone Scripts in New York State



Source: Buffalo News

362 *Id.*, p. 5, (citing Michel, L., and Schulman, S., “A Journey to Disaster.” *Buffalo News*, and Davis, H., “Study finds multiple pain killer prescriptions,” *Buffalo News*).

363 *Id.*, p. 6.

Map 2 – Hydrocodone Scripts in New York State*Source: Buffalo News*

1182. Defendants' creation, through false and deceptive advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed communities nationally. Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.³⁶⁴

1183. "In 2016, one out of every three beneficiaries received at least one prescription through Medicare Part D. In total, 14.4 million of the 43.6 million beneficiaries enrolled in Medicare Part D received opioids. Medicare part D paid almost \$4.1 billion for 79.4 million opioid prescriptions for those beneficiaries. The vast majority of these opioids (80 percent) were Schedule II or III controlled substances, meaning they have the highest potential for abuse among legally available drugs."³⁶⁵

1184. In New York State, "[o]ne beneficiary [of Medicare Part D] in New York received

³⁶⁴ See *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, Nathaniel Katz, et al, *American Journal of Managed Care*, April 19, 2013, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680126/>.

³⁶⁵ "HHS OIG Data Brief: OEI-02-17-00250," U.S. Department of Health and Human Services, Office of the Inspector General, Feb. 2017, p. 2, available at <https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf>.

62 opioid prescriptions during the year, which is more than one prescription per week. All of the prescriptions were for fentanyl or oxycodone. The beneficiary had an average daily morphine equivalent dose (“MED”) of over 3,130 mg for the entire year, which is almost 35 times the level that the CDC recommends avoiding. All but one of these opioids were prescribed by one family medicine physician.”³⁶⁶

1185. Contrary to Defendants’ misrepresentations, most opioid addiction begins with legitimately prescribed opioids, and therefore could have been prevented had Defendants’ representations to prescribers been truthful. As reported, in 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors’ prescribing habits have played in the opioid epidemic.

1186. Prescription drugs are connected with the rise of heroin use, so much so that “four in five new heroin users started out by misusing prescription opioids.”³⁶⁷ Users are switching from “prescription opioid painkillers, such as oxycodone or hydrocodone, to heroin because it’s easily accessible, cheaper, and offers a comparable high.”³⁶⁸

1187. The Manufacturer Defendants also purchased IMS Health data that informed the Manufacturers what the Distributors already knew from the data they provided to ARCOS and what the Manufacturers already knew from what they obtained in paying the Distributors chargebacks - that prescription opioids were flooding New York and City of Syracuse.

1188. Not surprisingly, several “pill mills” have been identified in New York, and

³⁶⁶ *Id.*, p. 5.

³⁶⁷ *Id.*

³⁶⁸ Bria Hillard, et al., “Battling the Rise of Heroin in Oneida County,” *Spike, Utica Watchdog Reporting*, available at <http://www.ucwatchdogreporting.com/heroinspike>.

prescription pain medication, including oxycodone and fentanyl, were prescribed, distributed and made their way to the streets, affecting New York and City of Syracuse residents.

1189. For example, Dr. Toby Taylor, a pain management specialist, was arrested in New York in June of 2017 on opioid related charges for allegedly running a pill mill and selling 4 million opioid pills to fake patients, along with two others accused of distributing the pills, Victor Gallicchio and Daniel Garcia.³⁶⁹

1190. In November of 2017, a New York doctor, Ernesto Lopez, his assistant, Audra Baker, and a pediatric nurse practitioner, Sharon Washington-Bhamre, were arrested on federal charges for writing thousands of phony prescriptions for fentanyl and oxycodone, in exchange for cash payments, where he would charge \$200-\$300 in cash for patient visits during which he performed perfunctory examinations and then prescribed large quantities of oxycodone and fentanyl patches. Since, 2015, Lopez wrote more than 8,000 prescriptions and collected \$2 million in fees according to federal prosecutors. It is alleged that patients were steered to an individual who could buy the prescriptions and resell the drugs on the street, according to court papers.³⁷⁰

1191. In April of 2017, an ex-state assemblyman, Alec Brook-Krasny, Dr. Lazar Feygin and 12 other people were arrested for running pill mill clinics and flooding the streets with 6.3 million prescription painkillers and received more than \$24 million in Medicare and Medicaid reimbursements.³⁷¹

1192. The Defendants were aware of specific “pill mills” and over- prescribers of their opioid drugs in New York State and City of Syracuse yet failed to report or halt suspicious orders to

³⁶⁹ Janice Williams, “Doctor Arrested in New York on Opioid Charges Signals Federal Crackdown on Pill Epidemic”, Friday, June 23, 2017; Web. 6 Dec. 2017.

³⁷⁰ Joe Valiquette, “Doctor Busted for Making Millions off Pill Mills in New York”. New York 4 TV. November 2, 2017, Web. 6 Dec. 2017

³⁷¹ Shayna Jacobs, Rich Shapiro, Daily News, “Ex State politician among 13 people busted for three Brooklyn clinic turned pill mills” Daily News, April 8, 2017; Web. 6 Dec. 2017

these entities, the foreseeable result of which was the diversion of opioids and the consequent damage to Plaintiff.

2. Opioids are Killing New Yorkers.

a. Prescription Opioid Abuse and its Effect on New York and City of Syracuse.

1193. The costs and consequences of opioid addiction are staggering. Prescription opioid misuse, abuse and overdose have an enormous impact on the health and safety of individuals as well as communities at large, as the consequences of this epidemic reach far beyond the individual who is addicted. Some of the repercussions for individuals include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration. This results in instability in communities often already in economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers and law enforcement.³⁷²

1194. Defendants knew and should have known about these harms that their deceptive marketing has caused. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew, and, indeed, intended that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain.

1195. Defendants' actions are not permitted nor excused by the fact that their drug labels (with the exception of the Actiq/Fentora labels) may have allowed or did not exclude the

³⁷² See *Prescription Opioid Abuse and Heroin Addiction in New York State*, report from the Office of the New York State Comptroller, June 2016.

use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

1196. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe - namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

1197. In New York State alone, between 2006 and 2016, the Department of Medicaid spent nearly \$175 million on Defendants' opioids. Many of these prescriptions were for chronic pain, and New York State would not have paid for them had Defendants told the truth about the risks and benefits of their drugs.

1198. Similarly, New York's Workers' Compensation paid for excessive opioid prescriptions due to Defendants' deceptive marketing practices. While the number of prescribed opioid prescriptions is slowly decreasing under the Workers Compensation program due to New York State efforts for reform, at \$450.90 per-user-per-year, opioids are the costliest class off medications for occupational injuries.³⁷³ Nationally, claims involving workers who take opioids are almost four times more likely to reach costs of over \$100,000 than claims involving workers without opioids because opioid patients suffer greater side effects and are slower to return to

³⁷³ See *Express Scripts: Workers' Comp Prescription Drug Spend Increases 2.2% in 2015*, *Claims Journal*, April 7, 2016, <https://www.claimsjournal.com/news/national/2016/04/07/269933.htm>

work.³⁷⁴ Even adjusting for injury severity and self-reported pain score, receiving an opioid for more than seven days and receiving more than one opioid prescription increased the risk that a patient will be on work disability one year later.³⁷⁵ A prescription for opioids as the first treatment for a workplace injury doubled the average length of the claim.³⁷⁶

1199. It is known that “Opioid pain-relievers are generally safe when taken for a short time and as prescribed by a doctor, but because they produce euphoria in addition to pain relief, they can be misused (taken in a different way or in larger quantity than prescribed or taken without a doctor’s prescription). Regular use - even as prescribed by a doctor - can lead to dependence, and when misused, opioid pain relievers can lead to overdose incidents and deaths.”³⁷⁷

1200. “According to [Substance Abuse and Mental Health Services Administration] SAMHSA’s 2014 National Survey on Drug Use and Health (NSDUH)... an estimated 43.6 million (18.1%) of Americans aged 18 and up experienced some form of mental illness. In the past year, 20.2 million adults (8.4%) had a substance use disorder. Of these, 7.9 million people had both a mental disorder and substance use disorder, also known as co-occurring mental and substance use disorders.”³⁷⁸

1201. As of September 2016, “1.4 million New Yorkers suffer[ed] from a substance abuse disorder.”³⁷⁹

1202. People who are addicted to prescription opioids are 40 times more likely to also be

³⁷⁴ *The Effect of Opioid Use on Workers' Compensation Claim Cost in the State of Michigan*, Jeffrey A. White, MS, *Journal of Occupational & Environmental Medicine*, August 2012.

³⁷⁵ See *Prescription Opioid Abuse and Heroin Addiction in New York State*, report from the Office of the New York State Comptroller, June 2016.

³⁷⁶ See Dongchun Wang, et al., *Longer-Term Use of Opioids*, *Workers Comp. Res. Inst.* (Oct. 2012).

³⁷⁷ “Opioids: Brief Description,” National Institute on Drug Abuse, available at <https://www.drugabuse.gov/drugs-abuse/opioids>.

³⁷⁸ “Mental and Substance Abuse Disorders,” *Topics*, Substance Abuse and Mental Health Services Administration, last updated 20 Sept. 2017, available at <https://www.samhsa.gov/disorders>.

³⁷⁹ “County Case Studies in Battling New York’s Heroin and Opioid Epidemic,” *New York State Association of Counties*, p. 2, Sep. 2016.

addicted to heroin.³⁸⁰



381

1203. “Overdose deaths in New York related to heroin use reached a record high of 825 in 2014, a jump of more than 23 percent from the previous year and nearly 25 times the number of a decade earlier... Comparing the death rates in 2005 and 2014 for both substances [heroin and prescription opioids], New York’s increased more than almost any other state for which such data were available.”³⁸²

1204. Increase in death rates related to heroin by state show that in New York State the death rate increased by 2,000 percent between 2005 and 2014. The death by prescription opioid rate in New York State rose by 250 percent during the same time period.³⁸³ In this time frame, “the age-adjusted rate of prescription opioid overdose deaths in New York nearly tripled, while the age-adjusted rate of heroin overdose deaths in the State increased twenty-fold.”³⁸⁴

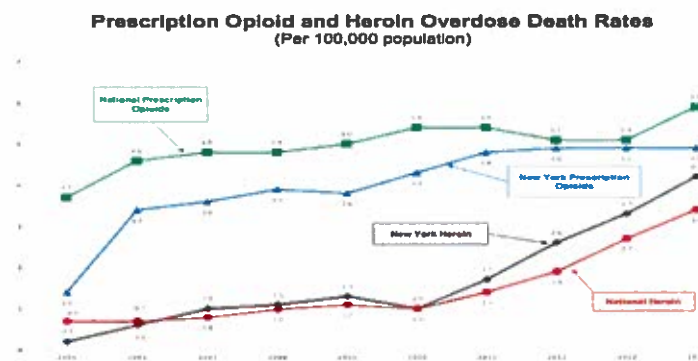
380 “Today’s Heroin Epidemic,” Centers for Disease Control and Prevention, available at <https://www.cdc.gov/vitalsigns/heroin/index.html>.

381 Combat Opioid Addiction, Onondaga County Health Department, <http://www.ongov.net/health/opioids>

382 Thomas P. DiNapoli “Prescription Opioid Abuse and Heroin Addiction in New York State,” “Message from the Comptroller,” New York State Office of the Comptroller, June 2016.

383 *Id.*, p. 5 (citing the CDC National Center for Health Statistics, available at <http://wonder.cdc.gov/mcd-icd10.html>).

384 *Id.*, p. 4.



Source: CDC, NCHS, Multiple Cause of Death on CDC WONDER Online Database, released 2015. Accessed at <http://wonder.cdc.gov/mcd lcd10.html> on December 9, 2015. Rates are age-adjusted by NCHS to facilitate comparisons over time or among groups, such as those living in different geographic areas. This type of measure eliminates differences that would be expected due to variations in age, such as higher or lower rates of heroin or opioid use.

1205. The death rate in New York from opioid drugs is “worse in upstate and suburban counties outside of New York City. There was a 45 percent increase in annual drug-related deaths in New York City, compared to an 84 percent increase in 17 counties outside of New York City.”³⁸⁵ According to the Center for Disease Control and Prevention, between 2010 and 2015, Onondaga County, in which the City of Syracuse is located, was one of these seventeen counties, along with Albany, Broome, Chautauqua, Dutchess, Erie, Monroe, Nassau, Niagara, Oneida, Orange, Oswego, Rensselaer, Rockland, Suffolk, Ulster and Westchester.³⁸⁶

1206. Onondaga County, in which the City of Syracuse is located, in particular, has a comparatively high death rate associated with heroin or opioids.³⁸⁷ Table 2 below shows the number of drug-related deaths per 100,000 people in each county from 2010 to 2015, and the increases in Onondaga County, in which the City of Syracuse is located. Table 3 below shows that the total drug deaths in Onondaga County, in which the City of Syracuse is located, have increased from 2010 to 2015 by 146%.³⁸⁸

³⁸⁵ “By the Numbers: The Growing Drug Epidemic in New York,” Rockefeller Institute of Government, April 2017, p. 2 (citing The Center for Disease Control and Prevention). (“The Growing Epidemic”).

³⁸⁶ *Id.*, p. 15.

³⁸⁷ Thomas P. DiNapoli “Prescription Opioid Abuse and Heroin Addiction in New York State,” New York State Office of the Comptroller, June 2016, p. 1.

³⁸⁸ “By the Numbers: The Growing Epidemic in New York,” Rockefeller Institute of Government, April 2017, p. 7, (citing the Center for Disease Control and Prevention, “Underlying Cause of Death 1995-2015”).

Table 2. 2010-2015 Drug-Related Death Rate Per 100,000, by NYS County*

	2010	2011	2012	2013	2014	2015
Albany	9.2	10.9	8.8	11.7	13.0	11.6
Bronx	13.0	14.1	15.1	15.4	14.7	20.4
Dutchess	19.8	12.8	20.9	24.2	18.9	22.0
Erie	8.9	12.5	10.3	15.2	18.6	31.7
Kings	7.6	8.5	9.0	8.4	9.7	10.3
Monroe	8.6	9.4	11.2	12.8	14.9	14.0
Nassau	8.6	11.5	12.2	12.6	13.1	15.4
New York	8.9	10.7	12.8	13.0	12.0	13.1
Niagara	14.8	11.6	16.3	19.1	17.8	24.9
Onondaga	8.8	10.1	13.5	14.5	17.1	21.6
Orange	17.2	15.2	15.2	17.3	19.1	19.9
Queens	6.4	6.6	6.5	8.5	7.1	7.8
Richmond	15.4	18.5	19.5	16.3	18.6	19.0
Rockland	6.4	6.3	6.6	10.6	8.8	11.3
Suffolk	13.7	19.0	18.4	18.8	18.2	19.6
Westchester	5.4	9.9	9.9	11.3	10.0	12.0

Centers for Disease Control and Prevention. National Center for Health Statistics. "Multiple Cause of Death 1999-2015." on CDC WONDER Online Database, released December 2016. Data are from the Multiple Cause of Death Data File, 1999-2015, as compiled from data provided by the fifty-seven vital statistics jurisdictions through the Vital Statistics Cooperative Program. <http://wonder.cdc.gov/mcd-4cd10.html>

389

Table 3. Total Drug Deaths by County Have Increased in New York State*

	2010	2011	2012	2013	2014	2015	% Increase 2010 to 2015
Albany	26	33	27	36	40	36	29%
Bronx	160	196	212	219	212	297	68%
Broome	19	26	22	34	42	40	111%
Chautauque	13	16	13	15	18	26	100%
Dutchess	59	38	62	72	50	65	10%
Erie	82	115	95	140	153	292	256%
Kings	191	216	230	219	254	272	42%
Monroe	64	70	84	96	112	105	64%
Nassau County	115	155	165	171	178	209	82%
New York	141	171	207	211	197	215	52%
Niagara	32	25	35	41	38	53	66%
Onondaga	41	47	63	68	80	101	146%
Orange	64	57	57	65	72	75	17%
Oswego	12	17	17	21	16	24	100%
Queens	142	148	148	166	164	183	29%
Richmond	72	87	92	77	86	90	25%
Rockland	20	20	21	34	22	37	86%
Suffolk	284	388	291	282	273	294	44%
Sutton	15	26	23	26	22	35	133%
Westchester	51	95	93	109	97	117	129%

Centers for Disease Control and Prevention. National Center for Health Statistics. "Underlying Cause of Death 1999-2015." on CDC WONDER Online Database, released December 2016. Data are from the Multiple Cause of Death Data File, 1999-2015, as compiled from data provided by the fifty-seven vital statistics jurisdictions through the Vital Statistics Cooperative Program. <http://wonder.cdc.gov/mcd-4cd10.html>

*These are the NYS counties that had complete data for every year. A full listing of the counties can be found in the Appendix.

390

Source: "By the Numbers: The Growing Epidemic in New York,"
Rockefeller Institute of Government, April, 2017

1207. "The increased use of prescription opioid medications, along with the widespread availability of cheap heroin and newer synthetic Fentanyl analogs, have contributed to a public health crisis in our community" said Indu Gupta, MD, MPH, MA, FACP, Commissioner of Health,

389 *Id.*390 *Id.*

Onondaga Health Department.³⁹¹

1208. “In New York State, overdose deaths involving opioids increased nearly 35 percent between 2015 and 2016. However, fentanyl-related deaths increased at a much higher rate, nearly 160 percent statewide: in New York City by more than 310 percent, and in counties outside of New York City by more than 110 percent.”³⁹²

1209. “Fentanyl is an opioid used in medicine as part of a surgical anesthetic and as a pain medication. When used illicitly or recreationally, it is often in the form of a pill (misabeled as an actual medication such as oxycontin), a liquid, or a white or brown powder.”³⁹³ “Heroin and cocaine containing deadly concentrations of fentanyl have been increasingly present in communities throughout the State. Fentanyl is also being pressed into pill form to resemble name-brand prescription opioids. Fentanyl analogs, or chemical variations, range in potency, but can be 100 times stronger than morphine. Just three milligrams of fentanyl can be fatal, compared to 30 milligrams of heroin.”³⁹⁴

1210. “An illicit version of Fentanyl... often mixed with heroin, helped fuel a big increase in drug overdose deaths in Onondaga County in 2016. Fentanyl can be 100 times more potent than heroin.”³⁹⁵

1211. “Research published in 2014 estimates that the U.S. societal costs of prescription opioid abuse, including direct medical costs and indirect costs for caregivers, the workplace, and the

³⁹¹ *Opioid-related deaths have tripled in Onondaga County since 2012, report shows*, Daniel Weber, CNY Central.com, September 27, 2017.

³⁹² “Press Release, Governor Cuomo Launches New Fentanyl Public Awareness Campaign,” November 21, 2017, Albany, <https://www.governor.ny.gov/news/governor-cuomo-launches-new-fentanyl-public-awareness-campaign>.

³⁹³ “Fentanyl,” New York State Office of Alcoholism and Substance Abuse Services, available at <https://www.oasas.ny.gov/CombatAddiction/Fentanyl.cfm>.

³⁹⁴ Press Release, Governor Cuomo Launches New Fentanyl Public Awareness Campaign, November 21, 2017, Albany, <https://www.governor.ny.gov/news/governor-cuomo-launches-new-fentanyl-public-awareness-campaign/>

³⁹⁵ “Onondaga County Opioid Epidemic Data Report,” Onondaga County Health Department, available at <https://insight.livestories.com/s/v2/onondaga-county-opioid-overdose-data/909863f4-ae57-46f3-b1b9-b6e6072b8781/>.

criminal justice system, at \$55.7 billion in 2007, well before the nation's recent surge in prescription opioid abuse."³⁹⁶

b. Impact on Services Offered by New York, Onondaga County and City of Syracuse

(i) Health Care Costs

1212. New York's total estimated health care costs from opioids, as of April 2015, was \$1,256 million, the 3rd highest among the states, making up 5.0% of abuse-related health care costs.³⁹⁷

TOP 10 STATES: TOTAL HEALTH CARE COSTS FROM OPIOID ABUSE



398

(ii) Opioid Related Emergency Calls/Emergency Department Visits

1213. New York State, Onondaga County and the City of Syracuse have seen a significant increase in opioid related emergency calls. Upstate New York Poison Center, Upstate Medical University, which is located in the City of Syracuse, provides help for the general public and healthcare professionals, and is staffed 24 hours per day, 7 days per week, and 365 days per year by RNs trained in toxicology, clinical (PharmD's) and medical toxicologists (MDs) and educators. "Heroin-related calls to Upstate Hospital's poison control center (Upstate Poison Center) surged by 417 percent from 29 in 2009 to 150 in 2013. Upstate Poison Center represents 54 counties in New

³⁹⁶ DiNapoli, Thomas P., "Prescription Opioid Abuse and Heroin Addiction in New York State," June 2016, p. 7.

³⁹⁷ "Health Care Costs from Opioid Abuse: A State-by-State Analysis," Matrix Global Advisors, LLC, April 2015, p. 5, https://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf, 1 Jan 2018.

³⁹⁸ *Id.*, p. 2-5.

York State,” including Onondaga County, in which the City of Syracuse is located. In 2013 alone, Upstate Poison Center received 84 of these of these emergency calls, two of which were fatal from Onondaga County, in which City of Syracuse is located.³⁹⁹ The chart below tracks the heroin and opioid calls received by the Upstate New York Poison Control from 2012 through 2015.

Heroin and Opioids Calls Upstate New York Poison Center

	2012		2013		2014		2015	
	54 CTY	ONON	54 CTY	ONON	54 CTY	ONON	54 CTY	ONON
Heroin	177	40	241	83	348	95	333	99
Opioids	3555	376	1337	213	2367	362	2366	247

The Upstate New York Poison Center provides educational information to the communities we serve.



400

1214. New York and City of Syracuse hospitals are seeing more cases of opioid overdose in hospital Emergency Departments (ED). In 2016 alone, there were 6,675 visits to New York State EDs (excluding New York City) due to opioid overdoses, including heroin. In 2016, there were 484 visits to Onondaga County EDs, nearly all of which are located in the City of Syracuse, due to opioid overdoses, including heroin, and 94 of these ED visits were for opioid overdoses including pharmaceutically and illicitly produced opioids such as fentanyl.⁴⁰¹

1215. “Emergency Department visit rates have increased from 2015 to 2016 in all

³⁹⁹“Joint Senate Task Force on Heroin and Opioid Addiction, Task Force Report: Solutions to New York’s Heroin Epidemic,” May 2014, p. 31 (citing Erie County Department of Health, Press Release).

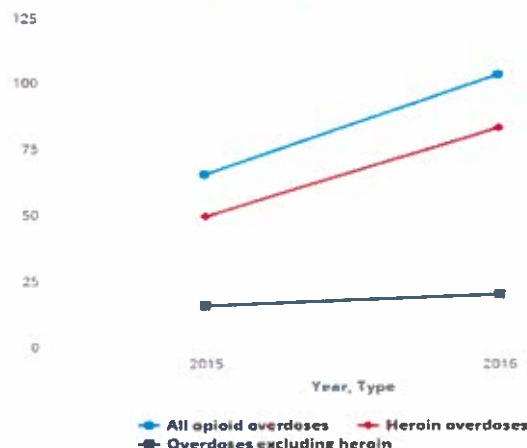
⁴⁰⁰ Opioid and Heroin Epidemic, Our Problem, Our Solutions, A Community Forum, presented by the Onondaga County Drug Task Force, <http://www.ongov.net/health/opioids/documents/HeroinForumSlides.pdf>

⁴⁰¹ “New York State- County Opioid Quarterly Report,” New York State Department of Health, Oct. 2017, p. 68, available at https://www.health.ny.gov/statistics/opioid/data/pdf/nys_oct17.pdf.

[opioid related] categories.⁴⁰² The crude rate for New York State was 59.4; whereas, in Onondaga County, in which the City of Syracuse is located, the crude rate for opioid overdoses, including heroin was 103.3.⁴⁰³

Figure 4: Opioid Overdose Emergency Department Visits Per 100,000 Population, Onondaga County, 2015 & 2016

Source: New York State-County Opioid Quarterly Report Published October 2017



1216. Previously, in 2015, in Onondaga County, in which the City of Syracuse is located, there were 307 outpatient emergency room visits for opioid-related overdoses.⁴⁰⁴ Since that time, it has been reported that, in Onondaga County, from January - September of 2017, there were 220 outpatient emergency room visits for opioid-related overdoses.⁴⁰⁵

(iii) Opioid-Related Hospital Admissions/Discharges

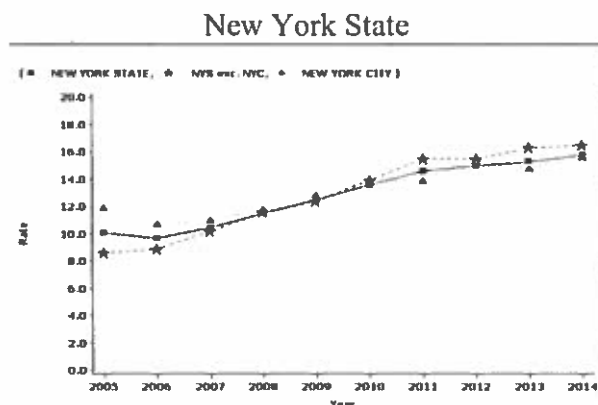
1217. The New York State Department of Health said it saw a 15.5 percent age-adjusted increase in hospital discharges involving any opioid overdose from 2012-2014, resulting in a total of 9,795 hospital discharges during the time period.

⁴⁰² "Onondaga County Opioid Epidemic Data Report," Onondaga County Health Department, available at <https://insight.livestories.com/s/v2/onondaga-county-opioid-overdose-data/909863f4-ae57-46f3-b1b9-b6e6072b8781/>.

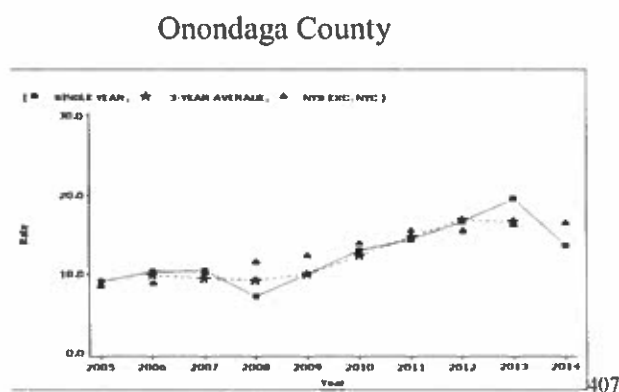
⁴⁰³ New York State- County Opioid Quarterly Report, Published October, 2017.

⁴⁰⁴ New York State – County Opioid Quarterly Report, Published April, 2017.

⁴⁰⁵ New York State- County Opioid Quarterly Report, Published October, 2017.



1218. In the same time frame, Onondaga County, in which the City of Syracuse is located, saw a 16.6 percent age-adjusted increase in hospital discharges involving opioid overdose, with 245 total discharges.⁴⁰⁶



1219. In Onondaga County, in which the City of Syracuse is located, in 2015, there were 94 hospitalizations for opioid-related overdoses,⁴⁰⁸ and, in 2016, there were 101 hospitalizations for opioid-related overdoses, and, from January – September of 2017 there were 66 hospitalizations for opioid-related overdoses.⁴⁰⁹

1220. Hospitalization rates in Onondaga County, in which the City of Syracuse is

⁴⁰⁶ "Hospital discharges involving any opioid overdose, rate per 100,000 population," New York State Department of Health, Revised Nov. 2017, available at <https://www.health.ny.gov/statistics/opioid/data/h2.htm>.

⁴⁰⁷ *Id.*

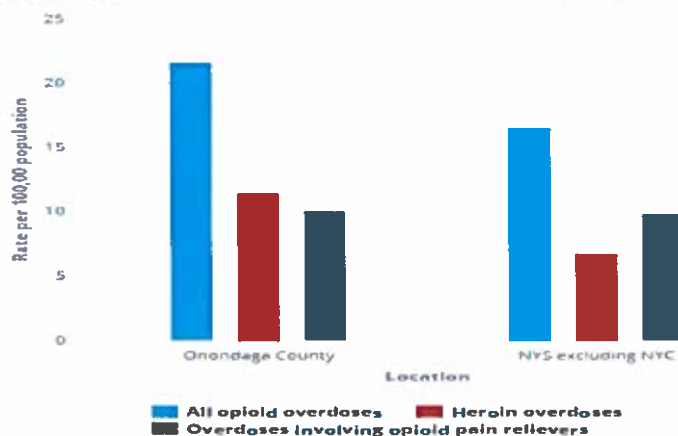
⁴⁰⁸ New York State – County Opioid Quarterly Report, Published April, 2017.

⁴⁰⁹ New York State – County Opioid Quarterly Report, Published October, 2017.

located, for opioid related overdoses are higher than New York States (excluding New York City).

Figure 5: Opioid Overdose Hospitalization Rates Per 100,000 Population, Onondaga County and NYS Excluding NYC, 2016

Source: New York State-County Opioid Quarterly Report Published July 2017



410

(iv) Overdose Deaths

1221. “A new report from Police Executive Research Forum (PERF), an independent research organization that focuses on ‘critical issues in policing,’” states “more Americans died from drug overdoses in 2016 than the number of American lives lost in the entirety of the Vietnam War, which totaled 58,200.”⁴¹¹ In New York, “[d]eaths in which prescription opioids were a contributing factor... reached a new peak in 2014, nearly four times the level in 2005.”⁴¹²

1222. The director of the CDC in 2015 estimated, based on 2010 data, “that for every opioid overdose death, there were 15 admissions into treatment for substance use disorders, 26 emergency room visits, 115 people who use or are dependent, and 733 non-medical users, resulting in

410 “Onondaga County Opioid Epidemic Data Report,” Onondaga County Health Department, available at <https://insight.livestories.com/s/v2/onondaga-county-opioid-overdose-data/909863f4-ae57-46f3-b1b9-b6e6072b8781/>.

411 “Drug Overdoses killed more Americans last year than the Vietnam War,” Ashley Welch, CBS News, October 17, 2017, <https://www.cbsnews.com/news/opioids-drug-overdose-killed-more-americans-last-year-than-the-vietnam-war/>.

412 DiNapoli, Thomas P., “Prescription Opioid Abuse and Heroin Addiction in New York State,” “Message from the Comptroller,” June 2016.

more than \$4.3 million in health care costs.”⁴¹³

1223. “Overdose deaths in which prescription opioids were a contributing cause totaled 1,008 in 2014.”⁴¹⁴ In 2005, “[p]rescription opioids were a factor in just less than 29 percent of drug overdose deaths... rising to more than 43 percent in 2014.”⁴¹⁵

1224. Since 2006, “New York’s heroin overdose rate has equaled or exceeded the national rate every year.”⁴¹⁶

1225. Overall, from 2010 to 2015 there was a 71 percent increase in drug death overdoses or from chronic drug abuse. In the same time frame, “14,173 people died from drugs in New York State. In the preceding six years (2004-2009), there were 9,754 total deaths.”⁴¹⁷

1226. In 2013, New York State saw 1,604 opioid overdose deaths, 1,710 deaths in 2014, and 2,185 in 2015. In those three years, the state saw a 36.22 percent increase in opioid overdose deaths.

1227. In Onondaga County, where the City of Syracuse is located, there were 44 opioid overdose deaths in 2013, and 59 opioid overdose deaths in 2014, and 78 opioid overdose deaths 2015. Onondaga County experienced a 48.94 percent increase in opioid overdose deaths from 2013 to 2015.

1228. The age-adjusted rates for both the State and Onondaga County, in which the City of Syracuse is located, are shown below.⁴¹⁸

413 “Opioid Misuse, Overdose, and Death: A National Public Health Emergency,” American Institutes for Research, p. 1, Oct. 2017, available at <https://www.air.org/sites/default/files/downloads/report/Opioid-Abuse-brochure-July-2017.pdf>.

414 DiNapoli, Thomas P., “Prescription Opioid Abuse and Heroin Addiction in New York State,” p. 1, June 2016.

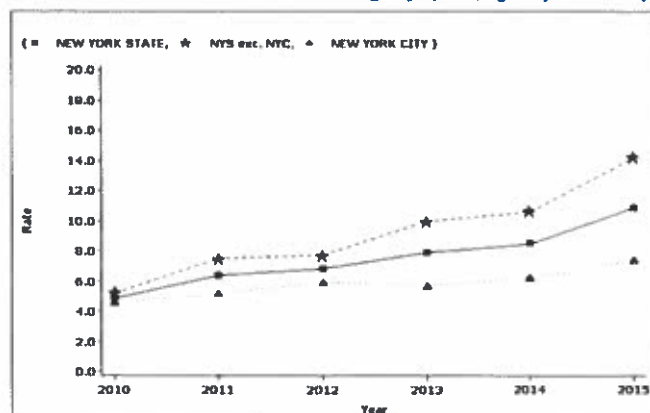
415 *Id.*, p. 5.

416 *Id.*, p. 1.

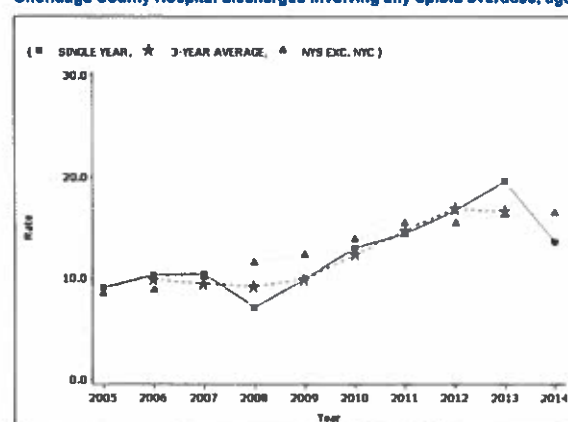
417 “By the Numbers: The Growing Epidemic in New York,” Rockefeller Institute of Government, April 2017, p. 4, (citing the Center for Disease Control and Prevention, “About Underlying Cause of Death 1995-2015”).

418 “Overdose deaths involving any opioid, rate per 100,000 population,” New York State Department of Health, available at <https://www.health.ny.gov/statistics/opioid/data/d2.htm>.

New York State Overdose deaths involving any opioid, age-adjusted rate per 100,000 population



Onondaga County Hospital discharges involving any opioid overdose, age-adjusted rate per 100,000 population



1229. “Onondaga County has the highest rate of opioid overdose deaths among Central New York Counties. The rate in Onondaga County is 17.5 per 10,000 population, compared to 11.0 per 10,000 population” for the rest of the State, excluding New York City.⁴¹⁹ Figure 1 below shows the breakdown of opioid-related deaths in Onondaga County, where the City of Syracuse is located, from 2012 to 2017. Whereas, Figure 2 below shows the breakdown of prescription related opioid deaths in Onondaga County through June 30, 2017.⁴²⁰

⁴¹⁹ “Onondaga County Opioid Epidemic Data Report,” Onondaga County Health Department, available at <https://insight.livestories.com/s/v2/onondaga-county-opioid-overdose-data/909863f4-ae57-46f3-b1b9-b6e6072b8781/>.

⁴²⁰ *Id.*

Source: Onondaga County Medical Examiner's Office

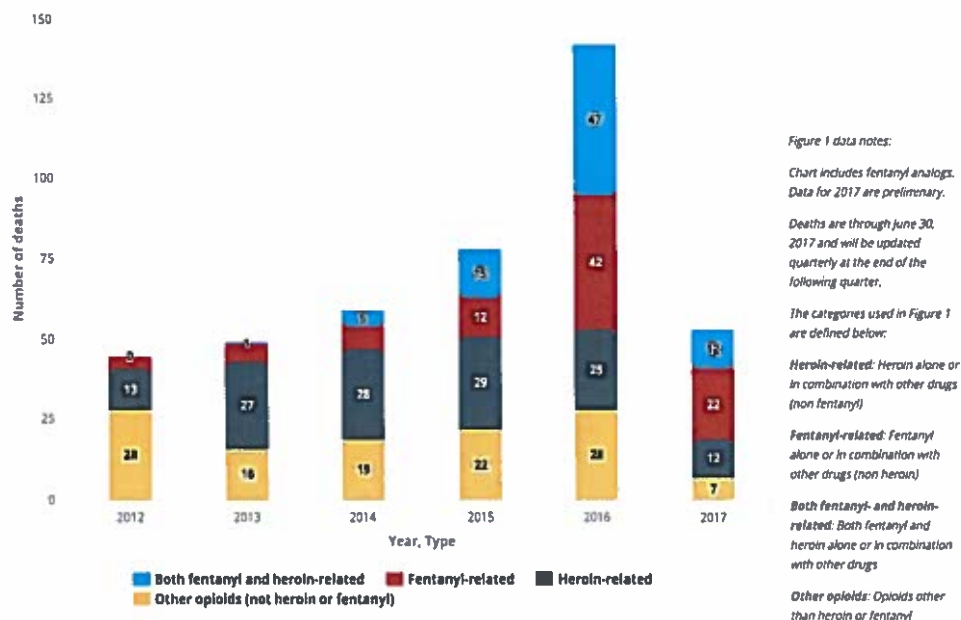


Figure 2: Unintended Prescription Opioid-Related Deaths in Onondaga County

Source: Onondaga County Medical Examiner's Office October 2017

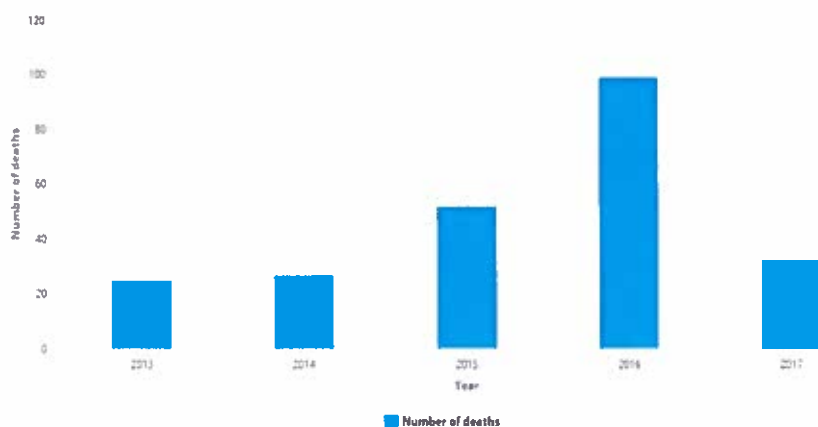


Figure 2 data notes. Data for 2017 are preliminary. Deaths are through June 30, 2017 and will be updated quarterly at the end of the following quarter. Deaths in Figure 2 are included in Figure 1 above.

(v) Increase in Costs for Law Enforcement and Training for Naloxone

1230. As already indicated, in Onondaga County, in which the City of Syracuse is located, law enforcement is involved in administering Naloxone in cases involving opioid overdoses. “Naloxone (brand name Narcan) is an opioid antagonist, meaning it neutralizes the pharmacological effects of an opioid in the body.... Naloxone reverses the effects of an opioid overdose, most

significantly, respiratory depression, which is the most common cause of death after drug overdose.”⁴²¹ In Onondaga County, where the City of Syracuse is located, alone there were 1,230 incidents in which naloxone was administered by EMS and law enforcement personnel during 2015 and 2016,⁴²² which breaks down as follows: Onondaga County law enforcement administered Narcan 33 times through December 31, 2015,⁴²³ 81 times through December 31, 2016, and 37 times through December 31, 2017;⁴²⁴ and, in Onondaga County, where the City of Syracuse is located, EMS has administered Naloxone 548 times through December 31, 2015,⁴²⁵ 568 times through December 31, 2016, and 180 times through December 31, 2017.⁴²⁶

1231. Dan Gigliotti, a Kunkel Paramedic, in Central New York, says “[p]aramedics are dispatched with police and fire, depending on the situation...If the situation is potentially dangerous, they have to ‘stage’ for law enforcement, meaning they have to hold back from entering until they arrive. This usually means waiting around the block for the “all clear” to go ahead. This is to ensure the security for their emergency services, says Gigliotti, so that they can deliver care” to the person who has overdosed. Because “Naloxone sends the addict into immediate withdrawal, they are often aggressive upon waking from the [opioid] reversal, which poses the chance of injury to the health care provider.” This is why law enforcement must be there, “because you never know what is going to happen when the person wakes up.” According to Gigliotti, “[Y]ou never judge a book by its cover.... [Y]ou could have the tiniest 18-year-old female come out of it and it takes four people to hold her down with the withdrawals. Or you could have the biggest of people, who are very well fit

⁴²¹ Bria Hillard, et al., “Battling the Rise of Heroin in Oneida County,” *Spike, Utica Watchdog Reporting*, available at <http://www.ucwatchdogreporting.com/heroinspike>.

⁴²² “New York State - County Opioid Quarterly Report,” New York State Department of Health, Oct. 2017, p. 67, available at https://www.health.ny.gov/statistics/opioid/data/pdf/nys_oct17.pdf.

⁴²³ New York State - County Opioid Quarterly Report, Published April, 2017.

⁴²⁴ New York State - County Opioid Quarterly Report, Published October, 2017; and April, 2018.

⁴²⁵ New York State - County Opioid Quarterly Report, Published April, 2017.

⁴²⁶ New York State - County Opioid Quarterly Report, Published October, 2017; and April, 2018.

come out of it, hug you, and say ‘thank you for saving my life.’”⁴²⁷

1232. According to a report put out by Syracuse.com, The Syracuse Fire Department paid \$47.50 per dose of naloxone in October of 2016. This price was more than 2 and a half times higher than what the department paid per dose of naloxone in 2013. “The department’s emergency medical technicians administered naloxone 132 times in 2015. By early September of [2016], they had already used it 156 times.”⁴²⁸ According to Lt. Brian Falise, *“the Syracuse Fire Department can go through \$1,000 worth of naloxone in a month.”*⁴²⁹ Falise explained that this is an expense that the Syracuse Fire Department must absorb this cost on their own.⁴³⁰

1233. Lon Fricano, the director of TLC—a private ambulance service that serves Onondaga County, in which the City of Syracuse is located, and the surrounding area, explained that *“overdose patients treated with naloxone are typically transported to a hospital for observation and further treatment. Many patients are uninsured and don’t pay the ambulance service bill.”*⁴³¹

1234. Between 2015 and 2016, there were a total of 15,361 incidents in which naloxone was administered by EMS and/or law enforcement personnel in New York State, excluding New York City.

1235. The distribution of naloxone throughout the state has been on a steady increase since 2006, indicating the growing dependence on overdose treatment throughout the State, as shown below.

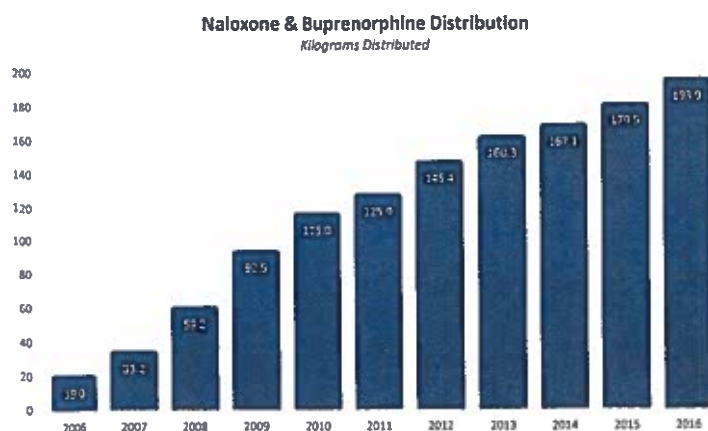
⁴²⁷ *Id.*

⁴²⁸ James T. Mulder, “Cost of Naloxone, The Life-Saving Drug in Heroin Battle, Soars as Epidemic Grows,” *Syracuse.com*, October 20, 2016. Available at https://www.syracuse.com/health/index.ssf/2016/10/heroin_1.html.

⁴²⁹ *Id.*

⁴³⁰ *Id.*

⁴³¹ *Id.*



◊ The increased distribution of Naloxone/Buprenorphine in New York is indicative of the trend and continued reliance on overdose prevention medication in all areas impacted by the opioid epidemic

432

1236. To help emergency personnel better respond to these calls, in August of 2014, the Governor of New York, Andrew Cuomo announced that “12 New York State Office of Alcoholism and Substance Abuse Services (OASAS) Addiction Treatment Centers (ATCs) in communities across the State [would] offer training sessions on opioid overdose prevention,” in which participants learned the signs of an overdose, what actions to take, and the proper way to administer naloxone. Once completed, participants received a free naloxone kit and certification to administer naloxone. The programs were open to first responders and the public, free of charge.⁴³³

1237. The State has also been working to double “the number of troopers working to arrest heroin traffickers and confiscate their drugs.”⁴³⁴

(vi) Syracuse Fire Department

1238. Defendants’ deceptive marketing schemes and practices has resulted in a

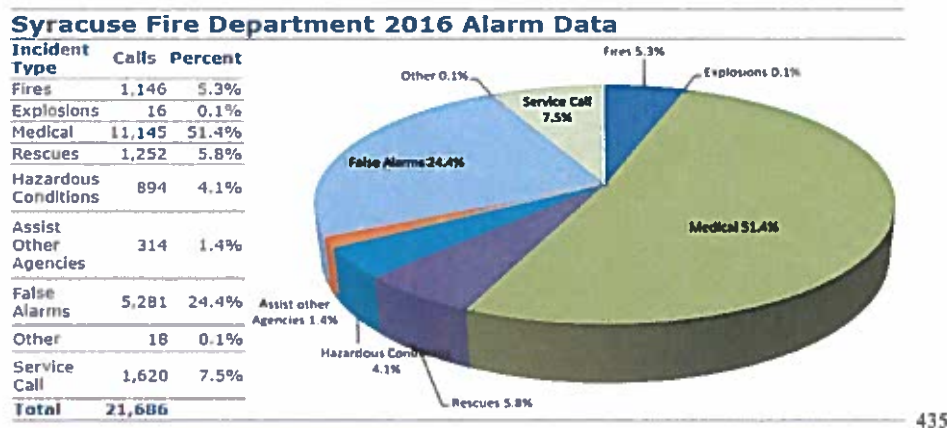
⁴³² New York State Associations of Counties, et al., “New York State Opioids Info Book,” Sept. 2017, p.14, (citing U.S. DOJ, available at <http://www.deadiversion.usdoj.gov/acros/index.html>).

⁴³³ “Governor Cuomo Announces Free Naloxone Training Sessions across New York State,” New York State, 8 Aug. 2014, available at <https://www.governor.ny.gov/news/governor-cuomo-announces-free-naloxone-training-sessions-across-new-york-state>

⁴³⁴ DiNapoli, Thomas P., “Prescription Opioid Abuse and Heroin Addiction in New York State,” New York State Office of the Comptroller, June 2016, p. 12 (citing <http://www.governor.ny.gov/news/governor-cuomo-announces-statewide-initiative-combat-heroin-use>).

significant financial burden to the Syracuse Fire Department due to a significant increase in the drug related work load being handled through the fire department.

1239. The following chart indicates that in 2016, 51.4% of the Syracuse Fire Department calls were for medical reasons, which included opioid and heroin overdoses:



1240. The Syracuse Fire Department has seen increased costs for employees' overtime and for medical supplies over time for drug related cases and for increased calls related to the opioid crisis that has affected the City of Syracuse and drug testing costs.

(vii) Increase in Drug Related Autopsies at the Onondaga County Medical Examiner's Office

1241. The Onondaga County Medical Examiner's Office, which is located in the City of Syracuse, completed "959 autopsies in 2016, up 106, or 12 percent, from 2015. Drug-related deaths accounted for 90 of the additional 106 autopsies last year. Drug-related deaths increased 50% in 2016." This is proving to be a huge problem in many counties across the state, including Onondaga County, because "[a]n ME's office can lose accreditation if each of its pathologists perform more than 325 autopsies per year... if the number of autopsies exceeds those thresholds, forensic pathologists may be more likely to take shortcuts and make mistakes... Dr. Robert Stoppacher,

435 http://www.syracuse.ny.us/Fire_Statistics.aspx

Onondaga County's chief medical examiner, recently told Onondaga County Legislature Health Committee members that using contract pathologists will help his office keep caseloads within the guidelines so it can maintain accreditation."⁴³⁶

1242. "Toxicology testing to identify the drugs taken by overdose victims is the most time-consuming part of drug related investigations, according to Stoppacher."⁴³⁷

1243. Per the Onondaga Medical Examiner's office, the number of opioid related deaths increased from 78 to 142 from 2015-16. These numbers have significantly increased from 2010 when there were almost none. The Onondaga County Medical Examiner Office's costs due to these opioid related deaths is estimated to have increased from \$290,872.84 in 2015 to \$488,616.39 in 2016, which estimation is based on per examination costs.

**(viii) Babies born with Neonatal Abstinence Syndrome/Health Related/
Foster Care Costs**

1244. Defendants' deceptive marketing scheme has also had a significant detrimental impact on children and newborns nationally and in New York State, Onondaga County and in the City of Syracuse. Reuters News Service identified 110 cases since 2010 of babies and toddlers whose mothers used opioids during pregnancy and who later died preventable deaths. Of those deaths, expectant mothers typically had been using heroin, synthetic painkillers that include such drugs as Percocet and OxyContin, or methadone, an opioid often prescribed as an alternative to heroin or the other medications.⁴³⁸ These children did not die because they were born drug-dependent. Every child had recovered sufficiently to be released from the hospital. These children

⁴³⁶ Mulder, James T., "Onondaga County seeks help to keep up with autopsies as drug overdoses soar," *Central NY Health, Syracuse.com*, 6 Jun., 2017, available at http://www.syracuse.com/health/index.ssf/2017/06/onondaga_county_medical_examiner_turns_to_nyc_for_help_in_drug_deaths.html.

⁴³⁷ *Id.*

⁴³⁸ See "Helpless and Hooked: The most vulnerable victims of America's opioid epidemic, Duff Wilson and John Shiffman, Reuters, December 7, 2015, www.reuters.com/investigates/special-report/baby-opioids/

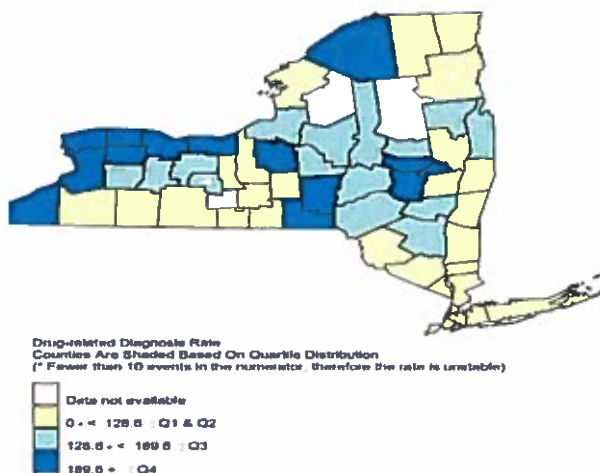
were killed because they were sent home with families that were not properly prepared to care for their new child.

1245. Entire families in New York, Onondaga County and the City of Syracuse are impacted by opioid use.

1246. In New York State, from 2012-2014 the average number of newborns was 229,488. During those years 7,214 infants were born with a drug-related diagnosis in the State. A State map below outlines the distribution of drug-related diagnoses in newborns throughout New York.

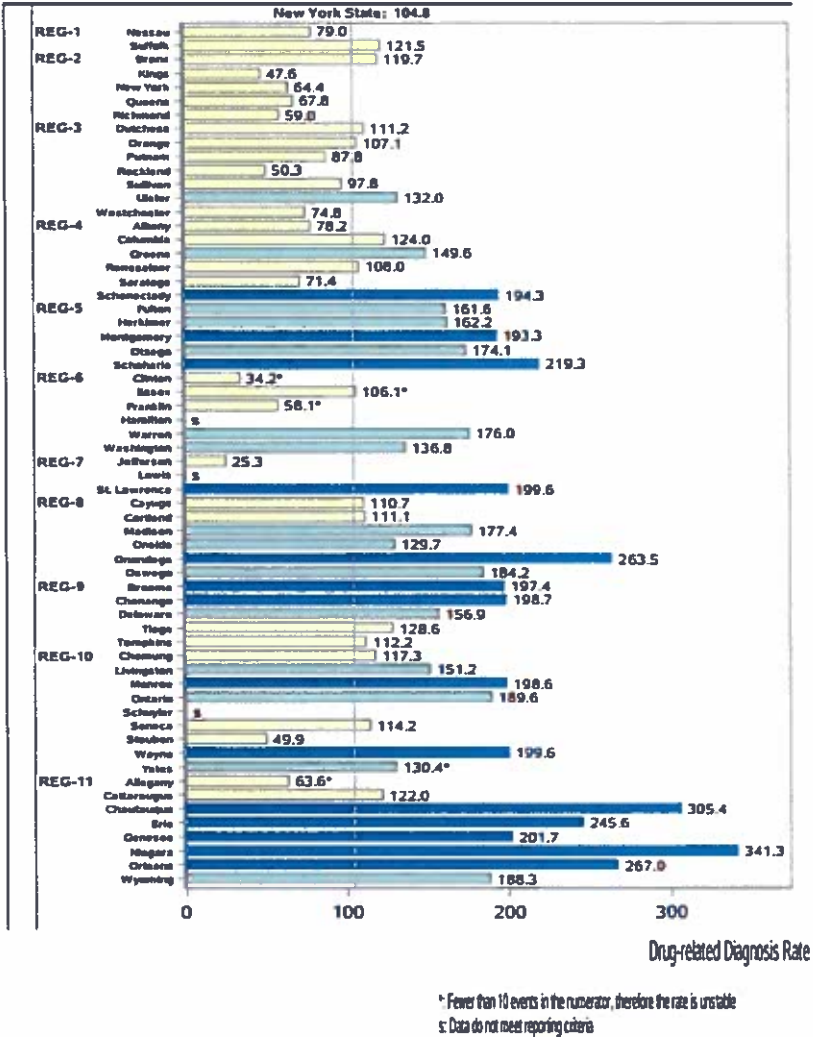
1247. The charts below demonstrate the crude rate of drug-related diagnoses in New York and Onondaga County.⁴³⁹

**Newborn drug-related diagnosis rate
per 10,000 newborn discharges
2012-2014**



Source: 2012-2014 SPARCS Data as of August, 2016

439 "New York State Community Health Indicator Reports- Maternal and Infant Health Indicators," New York State Department of Health, available at <https://www.health.ny.gov/statistics/chac/indicators/mih.htm>.

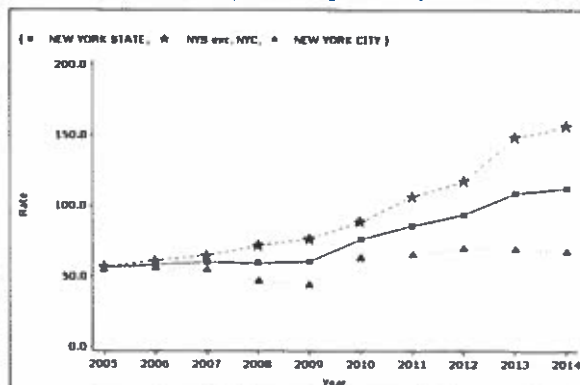


1248. The following charts show the New York State and Onondaga County drug related diagnosis rate per 10,000 newborns from 2005-2014.⁴⁴¹

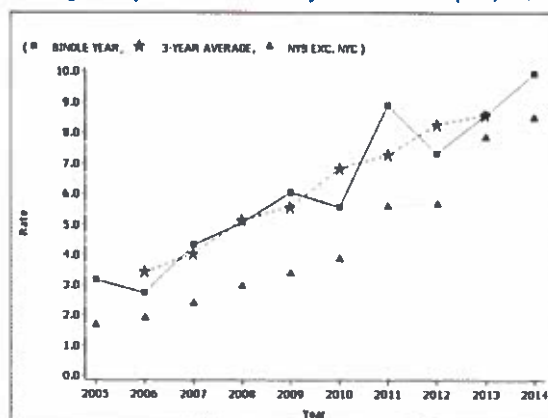
440 New York State Community Health Indicator Reports- Maternal and Infant Health Indicators," New York State Department of Health, <https://www.health.ny.gov/statistics/chac/hospital/pdf/h46.pdf>

441 Id.

New York State Newborn drug-related diagnosis rate per 10,000 newborn discharges



Onondaga County Neonatal abstinence syndrome crude rate per 1,000 newborn discharges (any diagnosis)



Onondaga County Neonatal abstinence syndrome crude rate per 1,000 newborn discharges (any diagnosis)

Year	Crude Rate		
	Single Year	3-Year Average	NYS exc. NYC
2005	3.2		1.7
2006	2.7	3.4	1.9
2007	4.4	4.1	2.4
2008	5.1	5.2	3.0
2009	6.1	5.6	3.4
2010	5.8	6.8	3.9
2011	8.9	7.3	6.6
2012	7.3	8.3	5.7
2013	8.6	8.6	7.9
2014	9.9		8.5

1249. New York State's rate of drug addicted newborns is 72.6 per 10,000 discharges; whereas, in Central New York the rate of drug addicted newborns is 130.5 per 10,000 discharges.⁴⁴²

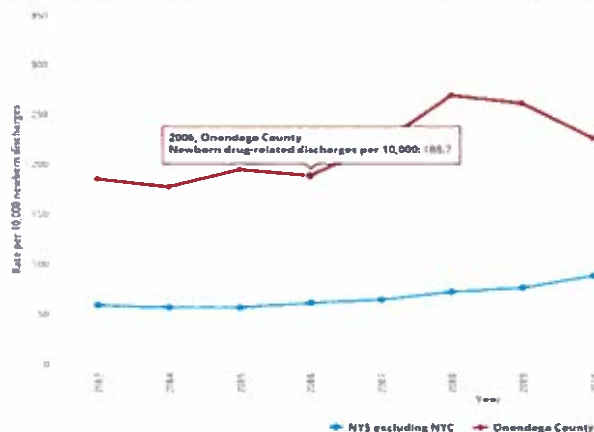
1250. Drug use impacts families in Onondaga County and in the City of Syracuse,

⁴⁴² *Id.*, p. 32.

including some of its youngest residents. “Onondaga County has the third highest rate in New York State for newborn drug-related diagnoses, with 300.6 drug-related diagnoses per 10,000 new born discharges in 2014.”⁴⁴³

Figure 6: Newborn Drug-Related Diagnosis Rate Per 10,000 Newborn Discharges, Onondaga County and NYS Excluding NYC, 2003-2014

Source: New York State Department of Health, Statewide Planning and Research Cooperative System (SPARCS)



444

Figure 7: Newborn Drug Related Diagnosis Rate Per 10,000 Newborn Discharges, NYS Counties, 2014

Source: New York State Department of Health, Statewide Planning and Research Cooperative System (SPARCS)

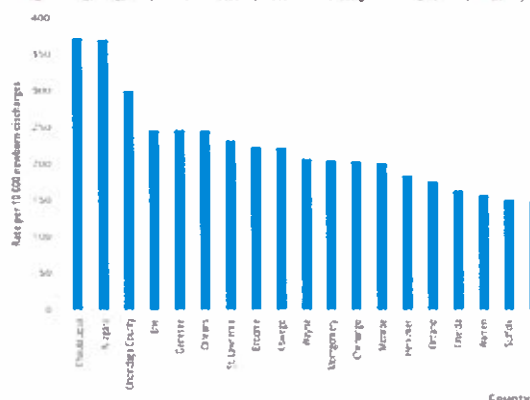


Figure 7 data note. In some counties data were suppressed because they did not meet the reporting criteria. These counties were excluded from the chart.

445

1251. “Neonatal abstinence syndrome (NAS) is one of the most concerning drug related discharges in newborns, according to the 2013 Onondaga County Community Health Assessment

⁴⁴³ “Onondaga County Opioid Epidemic Data Report,” Onondaga Health Department, available at <https://insight.livestories.com/s/v2/onondaga-county-opioid-overdose-data/909863f4-ae57-46f3-b1b9-b6e6072b8781/>.

⁴⁴⁴ *Id.*

⁴⁴⁵ *Id.*

Report.”⁴⁴⁶ “...NAS is a term for a group of problems a baby experiences when withdrawing from exposure to narcotics... Almost every drug passes from the mother's blood stream through the placenta to the fetus. Illicit substances that cause drug dependence and addiction in the mother also cause the fetus to become addicted. At birth, the baby's dependence on the substance continues. However, since the drug is no longer available, the baby's central nervous system becomes overstimulated causing the symptoms of withdrawal.” Symptoms of NAS are: “Tremors (trembling); Irritability (excessive crying); Sleep problems; High-pitched crying; Tight muscle tone; Hyperactive reflexes; Seizures; Yawning, stuffy nose, and sneezing; Poor feeding and sucking; Vomiting; Diarrhea; Dehydration; Sweating; Fever or unstable temperature.”⁴⁴⁷

1252. Central New York experiences newborn drug-related problems harshly. Onondaga County, where the City of Syracuse is located, has a rate of drug addicted newborns that “is four times higher than the state rate. ‘90% of the babies are born to women who are on Medicaid,’” according to Dr. Cynthia Morrow, the Onondaga County Health Commissioner, “[m]eaning that the taxpayer is footing the bill... If you look at the cost of a baby that’s born through normal delivery... and you look at a baby who’s born addicted to drugs who requires time in the intensive care unit, you’re talking \$8,000 versus \$50,000 for one baby.”⁴⁴⁸

1253. “In 2014, 40% of women seeking services [from Crouse Health Chemical Dependency Treatment Services in the City of Syracuse] were pregnant, in 2015 it increased to

446 *New York State Community Health Indicator Reports- Maternal and Infant Health Indicators*, New York State Department of Health, <https://www.health.ny.gov/statistics/chac/hospital/pdf/h46.pdf> p. 32, (citing <http://ongov.net/health/documents/OnondagaCounty2013CommunityHealthAssessment.pdf> Onondaga County Community Health Assessment 2014, p. 58).

447 “Neonatal Abstinence Syndrome,” *Stanford Children’s Health*, Lucile Packard Children’s Hospital- Stanford, available at <http://www.stanfordchildrens.org/en/topic/default?id=neonatal-abstinence-syndrome-90-P02387>.

448 “Joint Senate Task Force on Heroin and Opioid Addiction. Task Force Report: Solutions to New York’s Heroin Epidemic,” *New York State Senate*, p. 32, May 2014, available at https://www.nysenate.gov/sites/default/files/joint_senate_heroin_addiction_task_force_final_report_5-27-14.pdf, (citing <http://www.cnycentral.com/news/story.aspx?list=190258&id=1014814#.U0VkdflidUj4>).

52%... In 2013, Crouse cared for 59 NAS infants at a financial loss per case of over \$12,000. In 2015, that number increased to 70 NAS infants.”⁴⁴⁹

1254. According to a report published by *Syracuse.com* in 2012, “Twenty-eight babies were admitted to Crouse’s neonatal intensive care unit for drug withdrawal in 2011, up from nine in 2007. [Michelle Bode, a Crouse neonatologist expected] the number to climb even higher [in 2012] because Crouse already had 20 cases by early June. St. Joseph’s is seeing similar cases.”⁴⁵⁰ “Caring for the babies is labor intensive and costly. A typical newborn goes home from the hospital after two or three days. At Crouse, drug-dependent newborns stay in the NICU an average of 29 days. The cost of caring for one of these infants is about \$52,200. By comparison, the cost of caring for a typical newborn is about \$2,100.”⁴⁵¹

1255. Caring for babies experiencing the symptoms of withdrawal often requires time in the NICU, but such space in the NICU is very valuable and many doctors feel as though the NICU is not the best place for NAS babies. Doctors in Crouse and St. Joseph’s hospital in Syracuse are hoping to find a more appropriate setting for these newborns outside of the NICU. “Crouse’s NICU used to get one drug-dependent baby every month or two. [In 2012,] it typically [had] one to three babies in some stage of withdrawal, Bode said. Crouse often has more than 60 babies in its NICU. The babies going through withdrawal cannot be together. It’s too difficult for one nurse to care for two or three babies who are continuously screaming and rarely sleeping, Bode said. St. Joe’s has two isolation rooms in its NICU. Babies going through withdrawal are placed in those rooms if they are available.

449 Schultz, Rebecca, MPH., et al, “Onondaga County Community Health Assessment and Improvement Plan: 2016-2017,” p. 125, available at <http://www.ongov.net/health/documents/OnondagaCountyCHA-CHIP.pdf>

450 James T. Mulder, “Central New York’s Prescription-Drug Epidemic Creates State’s Highest Rate of Drug-Addicted Babies,” *Syracuse.com*, July 15, 2012. Available at https://www.syracuse.com/news/index.ssf/2012/07/central_new_yorks_prescription.html.

451 *Id.*

‘Space in the NICU is at a premium, and it’s not an easy environment to have a baby like this.’”⁴⁵²

1256. Beyond the devastating personal toll that NAS takes, a study conducted by the American Medical Association (AMA) in 2012 showed that the public cost of NAS is growing exponentially. In 2000, total hospital charges associated with NAS amounted to \$190 million; by 2009, they had risen to \$720 million, and about three quarters of these costs are financed through Medicaid. According to the U.S. Government Accountability Office (GAO), NAS infants stay in the hospital on average 16 days with an average hospital bill of \$53,000. Many families have no insurance, meaning that state and federally funded assistance programs along with taxpayers have to pay the costs to treat a drug-addicted baby.

1257. In January of 2016, U.S. Senator Schumer urged the federal government to immediately direct funds to Service providers, like Crouse Hospital in Syracuse, New York, to address the opioid epidemic.⁴⁵³ Schumer explained that Crouse Hospital in Syracuse is Central New York’s state-designated Regional Prenatal Center for 15 surrounding counties. As a result, the City of Syracuse sees a large number of sick infants. According to Crouse, the hospital’s neonatal intensive-care unit (NICU) has seen steady increases in babies born drug dependent over the last several years. In 2012, the NICU saw 26 babies born with drug dependency. By 2015, it saw 56 cases where infants were born dependent on opioids and other drugs. Schumer said this is an alarming, 100 percent increase and startling trend that must be stopped. In addition, the number of infants with an increase

⁴⁵² *Id.*

⁴⁵³ Press Release, Schumer: Onondaga County Has Second Highest Cases Of Infants Born Dependent On Rx Drugs & Opioids In Upstate NY – With New Anti-Drug Resources In Just-Passed Budget, Schumer Urges Feds To Immediately Direct Funds To Onondaga County Service Providers – Like Crouse Hospital – To Address This Epidemic; Number Of Drug-Dependent Babies Born At Crouse Up 100%, Jan. 6, 2016, https://www.schumer.senate.gov/newsroom/press-releases/schumer-onondaga-county-has-second-highest-cases-of-infants-born-dependent-on-rx-drugs-and-opioids-in-upstate-ny_with-new-anti-drug-resources-in-just-passed-budget-schumer-urges-feds-to-immediately-direct-funds-to-onondaga-county-service-providers--like-crouse-hospital--to-address-this-epidemic-number-of-drug-dependent-babies-born-at-crouse-up-100

in length of stay at Crouse on the general maternity floor as a result of in-utero exposure to opiates increased from 187 in 2012 to 297 in 2014. As of September of 2015, the hospital had already seen 237 cases in which infants were required to stay additional time on the maternity floor as a result of exposure to drugs and opioids.⁴⁵⁴

1258. "Opioid use during pregnancy comes at a cost to the baby - both in potential withdrawal symptoms as well as length of hospital admission," said researcher, Dr. Tammy Corr, a newborn medicine specialist at Penn State Hershey Medical Center. Dr. Corr states that pregnant woman addicted to opioids face tough barriers. "State policies vary in their treatment of pregnant women who have a substance abuse problem," Dr. Corr said. Those policies, she noted, range from offering women help with treatment, to criminalization. "Rather than treating substance abuse as a crime - which may discourage expectant mothers from seeking help, we need drug treatment programs that are specifically targeted to pregnant women," Dr. Corr said.⁴⁵⁵

1259. Moreover, not enough is known about the long-term effects of NAS. Children with NAS may experience developmental delays, or attention problems later in life.

1260. Research has found that children with NAS are more likely to end up in the foster care system.

1261. Between 2008 and 2013, 79,198 children in the State of New York were placed into foster care.⁴⁵⁶ According to the US Department of Health and Human Services, 273,539 children entered Foster Care during the 2016 Fiscal Year. In 34% of the cases, parent drug abuse was cited as a reason for removal, meaning that 92,107 children were removed from their homes due to parent

⁴⁵⁴ *Id.*

⁴⁵⁵ *Medical costs soar for U.S. babies born addicted to opioids*, Amy Norton, *Healthday Reporter*, June 15, 2017, <https://medicalxpress.com/news/2017-06-medical-soar-babies-born-addicted.html>

⁴⁵⁶ "Admissions into and Exits from Foster Care," New York State Office of Children and Family Services, *Child Welfare Report*, available at <http://ocfs.ny.gov/main/cfsr/counties.asp>.

drug addiction, nationally.⁴⁵⁷

1262. Further, the number of child abuse and neglect cases arising out of the opioid epidemic is buckling child welfare agencies across the state. The Plaintiff, CITY OF SYRACUSE's, youngest residents, who are abused and neglected because of the opioid epidemic, has created stress on the system - with caseworkers charged with keeping those youngsters safe often overwhelmed with more cases than they can handle, according to some of their advocates. Fueling rising caseloads in some counties, according to lawmakers and union officials, has been the epidemic of opiate addiction across upstate New York. "The opiate problem snowballed so quickly that nobody saw it coming," said Joe Musso, president of CSEA Local 884 for Clinton County's workers, including the county's Child Protective Services ("CPS") investigators. "When a mother or father becomes addicted, the entire family is impacted, and it's not a healthy environment for children to be in."⁴⁵⁸

1263. Per 2016-2017 data, the child welfare costs in Onondaga County, where the City of Syracuse is located, have increased due to the opioid-related epidemic. During that time frame, in Onondaga County, 22 children were removed from their homes and placed into foster care, specifically for cases in which a parent or parents were abusing opioids/heroin, which is in addition to the 20 children already in foster care related to parental opioid/heroin addictions. It is estimated that, in Onondaga County, there is an average daily population of approximately 30 children in foster care because of parental opioid/heroin related addictions with an annual cost of roughly \$1,030,000.00. This is only for foster care costs and does not include the cost of staffing of supervising these Onondaga County cases, which for 30 youth would be approximately 3 full time equivalent (FTE)

⁴⁵⁷ "The AFCRAS Report No. 24," *Adoption and Foster Care Analysis Reporting System*, p.1- 2, Nov. 2017, available at <https://www.acf.hhs.gov/sites/default/files/cb/afcarsreport24.pdf>.

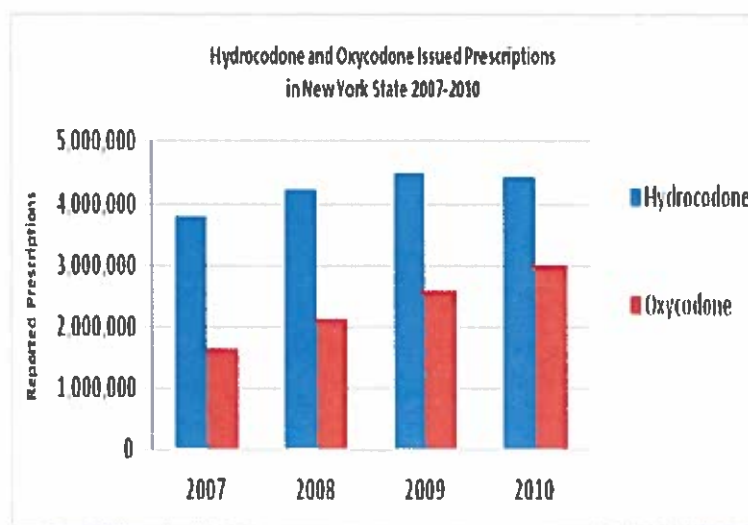
⁴⁵⁸ See *Child-protective workers warn system is swamped*, Joe Mahoney, *The Daily Star*, June 20, 2017, http://www.thedailystar.com/news/local_news/child-protective-workers-warn-system-is-swamped/article_1d6ea01b-5ccc-5bea-ad87-896d3cf1fec7.html.

caseworkers with an annual cost of \$300,000.00, plus additional services and court time.

(ix) Opioid Treatment Centers

1264. “Nationally, the treatment admission rate for opiates other than heroin increased from 10 to 53 admissions per thousand - an increase of 430 percent - from 1999 to 2009. New York was higher than the national average for that time period - 450 percent ranking the state 11th in the nation for admissions to chemical dependence programs for abuse of opioids other than heroin.

1265. Since 2007, when the state Bureau of Narcotic Enforcement (BNE) started collecting data on all narcotic prescriptions dispensed in the state, prescriptions for hydrocodone increased to 16.7 percent, while those for oxycodone increased to an astonishing 82 percent.”⁴⁵⁹



Data Source: NYS DOH, Bureau of Narcotics Enforcement

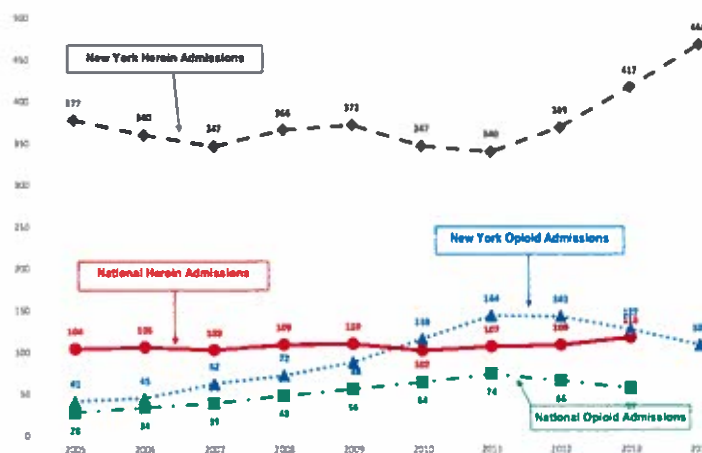
1266. Many New Yorkers are seeking treatment for opioid use. “Over the decade ending in 2014, the number and rate of treatment admissions for heroin use among New Yorkers aged 12 and older increased by over 20 percent. The number and rate of treatment admissions for prescription

⁴⁵⁹ “Internet System Tracking Over-Prescribing (I-STOP): A Proposal Addressing New York’s Diversion Epidemic,” New York State Office of the Attorney General, p. 4-5, (citing National Survey on Drug Use and Health (NSDUH), available at <http://oas.samhsa.gov/nsduhLatest.htm>).

opioid abuse in New York nearly doubled over the period.”⁴⁶⁰

1267. In fact, “compared to national averages, New Yorkers are significantly more likely to be admitted to treatment for heroin use or prescription opioid abuse. Factors in these trends may include New York’s higher-than-average rate of health insurance coverage and the State’s longstanding efforts to promote access to treatment.”⁴⁶¹

Treatment Admission Rates for Heroin and Prescription Opioids, New York and U.S.
(Individuals Aged 12 and Older, per 100,000 population)



Sources: Rates are per 100,000 population aged 12 and older. Substance Abuse and Mental Health Services Administration (SAMHSA) 2014 Treatment Episode Data Set Substance Abuse Treatment Admissions Tables as of the 2nd Quarter of 2015 Quarter, available at http://www.samhsa.gov/data/2k15/2k15_q2_sabst_treat_admissions_tables; SAMHSA 2014 Treatment Episode Data Set Substance Abuse Treatment Admissions Tables as of 2015 Q2 from SAMHSA, accessed on Dec. 3, 2015. Also see the SAMHSA Treatment Episode Data Set 2003-2013, available at http://wwwdata.samhsa.gov/data/2k13/2k13_q2_sabst_treat_admissions_tables. National data are not available for 2014.

1268. New York State has given significant funding for opioid treatment centers. “[T]he State Fiscal Year (SFY) 2016-2017 Enacted Budget provide[d] additional state funding of \$25 million to help localities develop, expand, and/or operate treatment, recovery, prevention and/or housing services for persons with heroin and opioid use disorders.”⁴⁶²

1269. The “OASAS (Office of Alcoholism and Substance Abuse Services) [was] also providing up to \$2 million for 50 new residential treatment beds” across the state “and ha[d] awarded

⁴⁶⁰ Thomas P. DiNapoli, “Prescription Opioid Abuse and Heroin Addiction in New York State,” New York State Office of the Comptroller, June 2016, p. 8.

⁴⁶¹ Id., “Message from the Comptroller”.

⁴⁶² DiNapoli, Thomas P., “Prescription Opioid Abuse and Heroin Addiction in New York State,” June 2016, p. 11.

\$1.6 million in annual funding to create adolescent substance abuse disorder clubhouses in seven regions across the State,”⁴⁶³ during the 2016-2017 SFY.

1270. Governor Cuomo has continued this funding. In the FY 2018 Budget, the State is “investing over \$200 million to support prevention, treatment, and recovery programs targeted toward chemical dependency, residential service opportunities, and public awareness and educational activities.”⁴⁶⁴

1271. “Treatment Centers in Central New York have reported that they’re running out of room to treat heroin addicted patients, as a doctor can only prescribe suboxone for up to 100 patients at a time.”⁴⁶⁵

1272. There are numerous treatment facilities in Syracuse, which have been overburdened with treating patients suffering from opioid addiction, including, CNY Services Dual Recovery Programs, Syracuse Recovery Services, Syracuse Behavioral Healthcare, Crouse Hospital - Chemical Dependency Treatment Services, Syracuse VA Medical Center, and in nearby communities, there is Tully Hill, located in Tully, New York, and Conifer Park, located in Liverpool, New York.

1273. In September of 2017, Governor Cuomo’s office announced that \$25.2 million in federal funding will be used to confront the ongoing opioid epidemic in New York State. The funding was awarded to the Office of Alcoholism and Substance Abuse Services (OASAS), through the Opioid State Targeted Response grant program administered by the Substance Abuse and Mental

⁴⁶³ *Id.*

⁴⁶⁴ “Governor Cuomo Announces Passage of the FY 2018 State Budget,” State of New York Budget Division, 10 Apr. 2017, available at <https://www.budget.ny.gov/pubs/press/2017/pressRelease17-enactedPassage.html>.

⁴⁶⁵ “Joint Senate Task Force on Heroin and Opioid Addiction. Task Force Report: Solutions to New York’s Heroin Epidemic,” New York State Senate, p. 31, May 2014, available at https://www.nysenate.gov/sites/default/files/joint_senate_heroin_addiction_task_force_final_report_5-27-14.pdf, (citing <http://www.wktv.com/news/top-stories/Heroin-use-on-the-rise-in-Oneida-County-233702441.html> WKTV, 11/27/13).

Health Services Administration, a branch of the U.S. Department of Health and Human Services. 16 counties across the state, designated as high-need areas, including Onondaga County, where the City of Syracuse is located, are to receive the funding to add and enhance treatment services for people with opioid use disorders. These services include mobile treatment, telehealth capabilities, and the expansion of medication assisted treatment, according to the Governor's office. The Governor's office says the 16 counties will share up to \$16 million to increase access to treatment, including Syracuse Brick House, which will receive \$1.8 million. In addition, several providers will receive \$100,000 to provide preventative services to at-risk populations, including, Central New York: Syracuse Model Neighborhood Facility, which is set to receive \$100,000.⁴⁶⁶

1274. Onondaga County, in which the City of Syracuse is located, has also seen a steady increase in adult treatment admissions over the past several years.

Adult Treatment Admissions

Figure 11: Unique Clients Admitted to OASAS-Certified Chemical Dependence Treatment Programs, by Admission Type, Onondaga County, 2015, 2016, & 2017 (through Q1)
Source: New York State County Opioid Quarterly Report Published Oct 2017

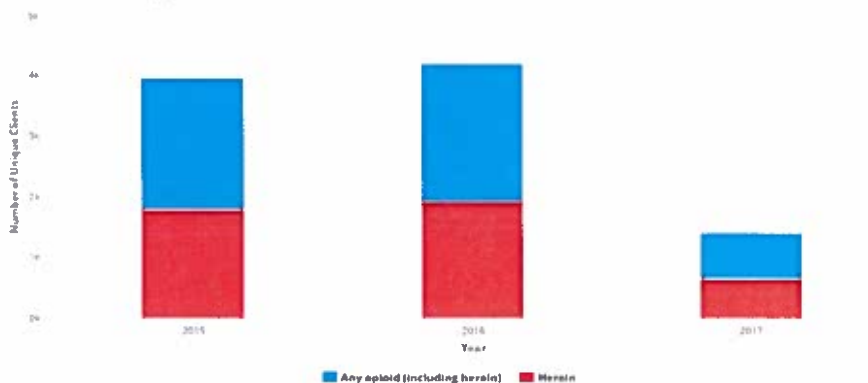


Figure 11 data note: Clients may have heroin, other opioids, or any other substance simultaneously recorded as the primary, secondary and tertiary substance of abuse in admission.

467

1275. In the City of Syracuse, Crouse Chemical Dependency Treatment Services

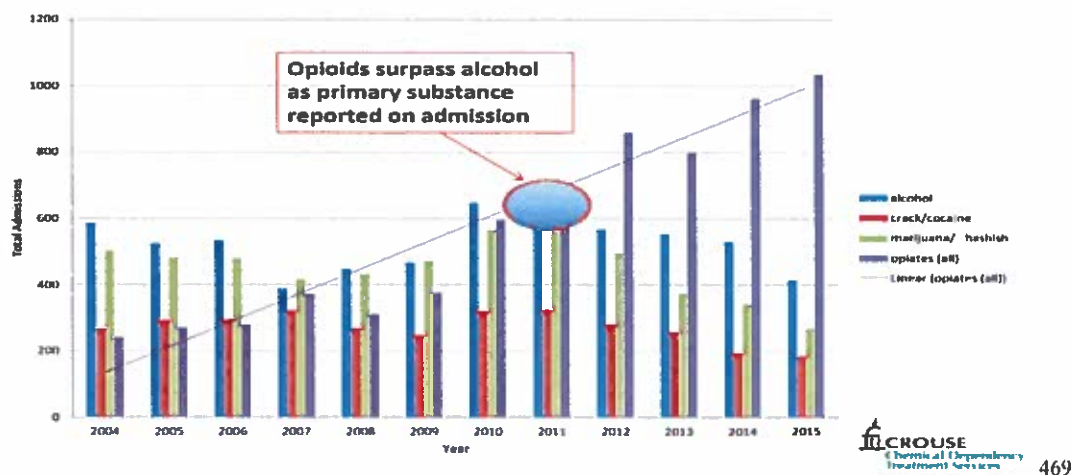
⁴⁶⁶ \$25 million in federal funding being used to address opioid crisis across NY, September 14th, 2017, <https://cnycentral.com/news/local/governor-cuomo-announces-25-million-in-funding-for-opioid-crisis>

⁴⁶⁷ New York State County Opioid Quarterly Report, Oct. 2017

("CDTS") is a 40-bed treatment facility for adults ages 18 and older. "As the only hospital-based treatment service, Crouse [Chemical Dependency Treatment Services] in 2015 logged 159,294 patient visits to the Opioid Treatment Program, with 200,413 outpatient visits overall. This is up from 2014, when there were 123,930 visits. The payer mix for the overall outpatient clinic and outpatient rehab is 75% Medicaid, 7% Medicare, 8% self-pay, 2% Medicare HMO and 9% commercial payers. Opioid Treatment Program is 71% Medicaid and Medicaid HMO; 10% self-pay, 3% Medicare and Medicare HMO, 8% Commercial. The Opioid Treatment Program serves 700 individuals."⁴⁶⁸

1276. CDTS reports that opioids have surpassed alcohol as primary substance reported on admission to their facility.

Admissions by Substance of Abuse



1277. Per Crouse, there has been a 64% increase in total admissions since 2010.

468 Schultz, Rebecca, MPH., et al, "Onondaga County Community Health Assessment and Improvement Plan: 2016-2017," p. 125, available at <http://www.ongov.net/health/documents/OnondagaCountyCHA-CHIP.pdf>.

469 Opioid and Heroin Epidemic, Our Problem, Our Solutions, A Community Forum, presented by the Onondaga County Drug Task Force, <http://www.ongov.net/health/opioids/documents/HeroinForumSlides.pdf>

Opioid Treatment Program Admissions

	2010	2015	
total admissions	156	250	64% increase
male	77	114	
female	79	142	
pregnant females	34	73	114% increase
Age			
18-21	10	8	
22-25	32	40	
26-35	65	135	107% increase
36-45	24	39	
46-55	20	24	
56+	5	10	

470

1278. While the use of opioids has taken an enormous toll nationwide, Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in revenue for drug companies like Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described above. All of this was done to the detriment of New York State and City of Syracuse residents.

(x) Onondaga County Sharps, Needles and Drug Disposal (SNADD) Programs

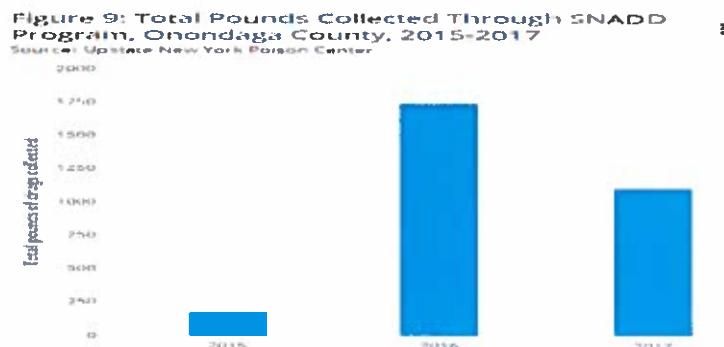
1279. Onondaga County, in which the City of Syracuse is located, sponsors a program called SNADD, to offer a solution for the safe disposal of household medications. Local participating police departments and colleges are collecting both over the counter and prescriptions medications during their regular business hours. The goal is to reduce the availability of drugs in the home, especially more dangerous drugs like opioid pain medication prescriptions. Onondaga County created this program to reduce the risk of ingestion, exposure and abuse of drugs in the county by providing residents of Onondaga County ways to dispose of their unwanted or outdated drugs.⁴⁷¹

1280. SNADD, since its inception in November of 2015, has collected 3,025 pounds

⁴⁷⁰ *Id.*

⁴⁷¹ *Combat Opioid Addiction, Onondaga County Health Department, <http://www.ongov.net/health/opioids>*

of drugs.⁴⁷² The 2017 totals only reflect pounds collected through June, 2017.⁴⁷³



TOLLING AND FRAUDULENT CONCEALMENT

1281. Plaintiffs continue to suffer harm from the unlawful actions by the Defendants.

1282. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

1283. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including New York State and Onondaga County, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. The Defendants affirmatively assured the public, including New York State and Onondaga County, that they are working to curb the opioid epidemic.

⁴⁷² "Onondaga County Opioid Epidemic Data Report," Onondaga County Health Department, available at <https://insight.livestories.com/s/v2/onondaga-county-opioid-overdose-data/909863f4-ae57-46f3-b1b9-b6e6072b8781/>.

⁴⁷³ *Id.*

1284. For example, a CARDINAL HEALTH executive said the company “deploys ‘advanced analytics, technology, and teams of anti-diversion specialists and investigators who are embedded in our supply chain. This ensures that we are as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.’”⁴⁷⁴

1285. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed a brief in *Masters Pharmaceuticals*, which made the following statements:

- “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”⁴⁷⁵
- “DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”⁴⁷⁶
- “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process. A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy. Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash.”⁴⁷⁷

1286. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the

⁴⁷⁴ Bernstein, Lenny et al., “How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: ‘No one was doing their job,’ *The Washington Post*, 22 Oct. 2016. Web. 6 Oct. 2017.

⁴⁷⁵ Brief for HDMA and NACDS filed in *Masters Pharm., Inc. v. Drug Enf’t Admin.*, USCA Case #15-1335, Doc. No. 1607110, p. 3 (D.C. Cir. Apr. 4, 2016).

⁴⁷⁶ *Id.*, at p. 4.

⁴⁷⁷ *Id.* at p 25.

Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further publicly affirmed that their conduct was in compliance with those obligations.

1287. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm the extent of their wrongful and illegal activities.

1288. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented the term “pseudoaddiction” and promoted it to an unsuspecting medical community. Manufacturer Defendants provided the medical community with false and misleading information about ineffectual medical strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids’ alleged benefits, disguising the risks, and promoting sales. The medical community, consumers, New York State and City of Syracuse were duped by the Manufacturer Defendants’ campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State of New York and in City of Syracuse.

1289. The Plaintiff reasonably relied on Defendants’ affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

1290. The Plaintiff’s claims are equitably tolled because Defendants knowingly and fraudulently concealed the facts, and concealed their wrongful acts, along with the material information pertinent to their discovery, from the federal and state agencies and the Plaintiff herein. The Plaintiff did not know, or could not have known through the exercise of reasonable diligence, of their claims, as a result of Defendants’ actions and conduct.

1291. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

1292. In light of their statements to the media, in legal filings, and settlements, Defendants had actual and constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

1293. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, Plaintiffs were unable to obtain vital information bearing on their claims absent any fault or lack of diligence on their part.

**COUNT I:
PUBLIC NUISANCE
(AGAINST ALL DEFENDANTS)**

1294. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

1295. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of a considerable number of persons in City of Syracuse by their production, promotion, and marketing of opioids for use by residents of City of Syracuse.

1296. The law of public nuisance is best viewed as shifting the resulting cost of a public nuisance from the general public to the party who creates it. If the marketplace values the product sufficiently to accept that cost, the manufacturer can price it into the product. If the manufacturers

and users of the offending activity conclude that the activity is not worthwhile after absorbing these costs, that is their choice. In either case, there is no injustice in requiring the activity to tailor itself to accept the costs imposed on others or cease generating them.

1297. The essence of a nuisance claim is the foreseeable harm unreasonably created by the defendants' conduct.

1298. Defendants' activities have been, and continue to be, (1) injurious to health; (2) indecent; (3) offensive to the senses; or (4) an obstruction to the free use of property; so as essentially to interfere with the comfortable enjoyment of life and property, and constitute a nuisance.

1299. Additionally, Defendants have created a public nuisance by creating an unreasonable interference with rights common to the general public in that:

- a. Defendants' conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort, and the public convenience;
- b. Defendants' conduct is proscribed by statutes, ordinances, and administrative regulations; and
- c. Defendants' conduct is of a continuing nature and has produced a permanent and long-lasting effect, and Defendants know, and have reason to know, that their conduct has a significant effect upon public rights.

1300. All Defendants are subject to liability because each Defendant has participated to a substantial extent in carrying out the activities that are the public nuisance.

1301. Defendants' conduct is unreasonable.

1302. Defendants' conduct is not insubstantial or fleeting. It has caused deaths, serious injuries, and a severe disruption of public peace, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.

1303. Defendants' conduct constitutes a public nuisance.

1304. Defendants' conduct directly and proximately caused injury to Plaintiff and its

residents.

1305. Plaintiff and its residents suffered special injuries distinguishable from those suffered by the general public.

**COUNT II:
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS
ACT, 18 U.S.C. § 1961, ET SEQ.
(AGAINST ALL DEFENDANTS)**

1306. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

1307. Plaintiffs bring this Count against all Defendants.

1308. The Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise or a legal entity enterprise. At all relevant times, the Defendants were “persons” under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, “a legal or beneficial interest in property.”

1309. Section 1962(c) of RICO makes it unlawful “for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity or collection of unlawful debt.” 18 U.S.C. § 1962(c); *United State v. Turkette*, 452 U.S. 576, 580 (1981).

1310. The term “enterprise” includes “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. United States*, 556 U.S. 938, 944 (2009); *United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 853 (7th Cir. 2013). The definition of “enterprise” in Section 1961(4) includes both legitimate and illegitimate enterprises. Specifically, the section “describes two

separate categories of associations that come within the purview of an ‘enterprise’—the first encompassing organizations such as corporations, partnerships, and other ‘legal entities,’ and the second covering ‘any union or group of individuals associated in fact although not a legal entity.’” *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id.*

1311. For over a decade, the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As “registrants,” the Defendants operated and continue to operate within the “closed-system” created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the “CSA”). The CSA restricts the Defendants’ ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

1312. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from “legitimate channels of trade” to the illicit market “by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances].”⁴⁷⁸

1313. Finding it impossible to legally achieve their ever-increasing sales ambitions,

⁴⁷⁸ 1970 U.S.C.C.A.N. 4566 at 5490; see also Testimony of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drugcaucus.senate.gov, U.S. Dept. of Justice, Drug Enforcement Administration, Before the Caucus on International Narcotics Control, United States Senate, 5 May 2015 (“Rannazzisi May 5, 2015 Testimony”). Web. 25 Oct. 2017.

members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.⁴⁷⁹ As discussed in detail below, through the Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.⁴⁸⁰ In doing so, the Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate enormous profits.

1314. Defendants' illegal scheme was implemented by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed by each of them. In particular, each of the Defendants was associated with, and conducted or participated in, the affairs of the RICO enterprise, whose purpose was to engage in the unlawful sales of opioids, deceive the public, and deceive both federal and state regulators, into believing that the Defendants were faithfully fulfilling their statutory obligations. The Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while New York State and City of Syracuse suffered injury caused by the reasonably foreseeable consequences of the opioid epidemic. As explained in detail below, the Defendants' misconduct violated Section 1962(c) and Plaintiffs are entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

⁴⁷⁹ 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

⁴⁸⁰ 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

1315. Alternatively, the Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the HDA’’) ⁴⁸¹ is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an “enterprise” within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

1316. The Defendants are members, participants, and/or sponsors of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

1317. Each of the Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the Defendants exists separately from the HDA. Therefore, the HDA itself serves as a RICO enterprise.

1318. The legal and association-in-fact enterprises were each used by the Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises are pleaded in the alternative and are collectively referred to as the “Opioid Diversion Enterprise.”

A. The Opioid Diversion Enterprise

1319. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, to design and operate a system to disclose suspicious orders, and to inform the

⁴⁸¹ *Health Distribution Alliance, History, Health Distribution Alliance*, <https://www.healthcaredistribution.org/about/hda-history>. Web. 11 Oct. 2017.

DEA of any suspicious orders.⁴⁸² The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to know their customers.⁴⁸³

1320. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.”⁴⁸⁴ When evaluating production quotas, the DEA was instructed to consider the following information:

- a. Information provided by the Department of Health and Human Services;
- b. Total net disposal of the basic class by all manufacturers;
- c. Trends in the national rate of disposal of the basic class;
- d. An applicant’s production cycle and current inventory position;
- e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and
- f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.⁴⁸⁵

1321. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota

⁴⁸² Joseph T. Rannazzisi, *In Reference to Registration # RC0183080* (Sept. 27, 2006); Joseph T. Rannazzisi, *In Reference to Registration # RC0183080* (Dec. 27, 2007).

⁴⁸³ See “Suggested Questions a Distributor should ask prior to Shipping Controlled Substances, *Dea*diversion.usdoj.gov/, U.S. Dept. of Justice, Drug Enforcement Administration. Web. 11 Oct. 2017.

⁴⁸⁴ Rannazzisi May 5, 2015 Testimony, at p. 3.

⁴⁸⁵ Rannazzisi May 5, 2015 Testimony, at p. 3.

assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.⁴⁸⁶

1322. At all relevant times, the Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by disregarding their statutory duty to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

1323. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. *Turkette*, 452 U.S. at 580; *Boyle*, 556 U.S. at 944. Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the Defendants would have a larger pool of prescription opioids from which to profit.

1324. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the Defendants liable for disregarding their duty to prevent diversion.

⁴⁸⁶ *Id.*, at p. 4 (citing 21 U.S.C. 842(b)).

Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance (“HDA”) lobbied for the passage of legislation to weaken the DEA’s enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA’s ability to issue orders to show cause and to suspend and/or revoke registrations.⁴⁸⁷ The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties. The Pain Care Forum and its members spent significant funds on lobbying efforts while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

1325. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants’ scheme was to increase profits from opioid sales. But, Defendants’ profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate, and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

⁴⁸⁷ See “HDMA is now the Healthcare Distribution Alliance,” *Pharmaceuticalcommerce.com*, 13 June 2016, updated 6 July 2016. Web. 11 Oct. 2017; Bernstein, Lenny et al, “Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control,” *The Washington Post*, 22 Oct. 2016. Web. 6 Oct. 2017; Higham, Scott et al., “U.S. Senator Calls for Investigation of DEA Enforcement Slowdown amid Opioid Crisis,” *The Washington Post*, 6 Mar. 2017. Web. 11 Oct. 2017; Eyre, Eric, “DEA Agent: ‘We Had no Leadership’ in West Virginia Amid Flood of Pain Pills,” *100daysinappalachia.com/*. Web. 25 Oct. 2017.

1326. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

1327. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

1328. Each of the Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. The Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

1329. The Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

1330. The Pain Care Forum (“PCF”) has been described as a coalition of drug makers, trade groups, and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

1331. The Center for Public Integrity and the Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”⁴⁸⁸ Specifically, PCF participants spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.⁴⁸⁹

1332. Not surprisingly, each of the Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.⁴⁹⁰ In 2012, membership and participating organizations included the HDA (of which all Defendants are members), ENDO, PURDUE, Johnson & Johnson, ACTAVIS, and Teva.⁴⁹¹ Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.⁴⁹²

1333. The 2012 Meeting Schedule for the PCF is specific example of the Defendants’ interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were “encouraged to attend in person” at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a “Guest Speaker.”

⁴⁸⁸ Perrone, Matthew, “Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic,” *The Center for Public Integrity*, 19 Sept. 2016, updated 15 Dec. 2016. Web. 25 Oct. 2017.

⁴⁸⁹ *Id.*

⁴⁹⁰ PAIN CARE FORUM 2012 Meetings Schedule, <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>, last updated Dec. 2011. Web. 11 Oct. 2017

⁴⁹¹ *Id.*

⁴⁹² *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for CARDINAL HEALTH, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AMERISOURCEBERGEN Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. See “Executive Committee, Healthcare Distribution Alliance,” Healthcaredistribution.org, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

1334. The 2012 PCF Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug makers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

1335. Second, the HDA led to the formation of interpersonal relationships and an organization between the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants are members.⁴⁹³ And, the HDA and each of the Distributor Defendants sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

1336. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”⁴⁹⁴ The HDA and the Distributor Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturer and Distributor Defendants.

1337. The application for manufacturer membership in the HDA further indicates the

⁴⁹³ “Manufacturer Membership,” *Healthcaredistribution.org*, Healthcare Distribution Alliance, Web. 11 Oct. 2017.

⁴⁹⁴ “Manufacturer Membership Benefits,” *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

level of connection that existed between the Defendants.⁴⁹⁵ The manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AMERISOURCEBERGEN, CARDINAL HEALTH, and MCKESSON.⁴⁹⁶

1338. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, which promoted the Opioid Diversion Enterprise efforts, including lobbying and even development of chargebacks, including:

1339. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”⁴⁹⁷

- a. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributors and manufacturer members.⁴⁹⁸
- b. Health, Beauty and Wellness Committee: “This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain.” Participation in this committee includes distributors and manufacturer members.⁴⁹⁹
- c. Logistics Operation Committee: “This committee initiates projects designed

⁴⁹⁵ *Manufacturer Membership Application Instructions*, Healthcaredistribution.org, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

⁴⁹⁶ *Id.*

⁴⁹⁷ *“Councils and Committees,”* Healthcaredistribution.org, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

⁴⁹⁸ *Id.*

⁴⁹⁹ *Id.*

to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributors and manufacturer members.⁵⁰⁰

- d. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.⁵⁰¹
- e. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.⁵⁰²
- f. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.⁵⁰³
- g. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.⁵⁰⁴
- h. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation includes Distributor and Manufacturer Members.⁵⁰⁵

1340. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise’s organization.

1341. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the

⁵⁰⁰ *Id.*

⁵⁰¹ *Id.*

⁵⁰² *Id.*

⁵⁰³ *Id.*

⁵⁰⁴ *Id.*

⁵⁰⁵ *Id.*

Manufacturer Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.”⁵⁰⁶ The conferences also gave the Manufacturer and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.”⁵⁰⁷ The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. It is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.⁵⁰⁸

1342. Third, the Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

1343. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and chargebacks to the Distributor Defendants for sales of prescription opioids.⁵⁰⁹ As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturer Defendants paid the Distributor Defendants rebates and/or chargebacks on their prescription opioid sales.⁵¹⁰ These contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor

⁵⁰⁶ “Business and Leadership Conference – Information for Manufacturers,” *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

⁵⁰⁷ *Id.*

⁵⁰⁸ See “2015 Distribution Management Conference and Expo,” Healthcare Distribution Alliance, *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

⁵⁰⁹ See Bernstein, Lenny et al., “The Government’s Struggle to Hold Opioid Manufacturers Accountable,” *The Washington Post*, 2 Apr. 2017. Web. 12 Oct. 2017. See also Letter from Sen. Claire McCaskill, <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>, 26 July 2017. Web. 12 Oct. 2017; “Behind an Epidemic: Opioid Manufacturers Subject of New McCaskill Investigation, *Mccaskill.senate.gov*. Web. 12 Oct. 2017; “Purdue Managed Markets,” *Purduepharma.com*, Purdue Pharma. Web. 12 Oct. 2017.

⁵¹⁰ *Id.*

Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.⁵¹¹ The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

1344. The contractual relationships among the Defendants also include vault security programs. The Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. Manufacturers likely negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and anti-diversion duties.

1345. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the PCF are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the groups of Defendants were in communication and cooperation.

1346. According to articles published by the Center for Public Integrity and The Associated Press, the PCF has been lobbying on behalf of the Manufacturer and Distributor

⁵¹¹ See "Webinar Leveraging EDI: Order-to-Cash Transactions CD Box Set," *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

Defendants for “more than a decade.”⁵¹² From 2006 to 2016 the Distributor and Manufacturer Defendants worked together through the PCF to spend over \$740 million lobbying in the nation’s capital and in all 50 statehouses on issues including opioid-related measures.⁵¹³ Similarly, the HDA has continued its work on behalf of Defendants, without interruption, since at least 2000, if not longer.⁵¹⁴

1347. As described above, the Defendants began working together as early as 2006 through the Pain Care Forum and the HDA to promote the common purpose of their enterprise. Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. Conduct of the Opioid Diversion Enterprise

1348. During the time period alleged in this Complaint, the Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise, by fraudulently failing to comply with their Federal and State obligations to: (i) identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market; (ii) halt such unlawful sales; and (iii) increasing production quotas and generate unlawful profits, as set forth herein.

1349. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

1350. Defendants disseminated false and misleading statements to the public claiming

⁵¹² Perrone, Matthew, “Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic,” *The Center for Public Integrity*, 19 Sept. 2016, updated 15 Dec. 2016. Web. 25 Oct. 2017.

⁵¹³ *Id.*

⁵¹⁴ “History,” *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

1351. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

1352. Defendants paid nearly \$800 million dollars to influence local, state, and federal governments through joint lobbying efforts as part of the Pain Care Forum. The Defendants were all members of the PCF either directly, or indirectly, through the HDA. The lobbying efforts of the PCF and its members included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

1353. The Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

1354. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids, and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."⁵¹⁵

1355. The Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. The Manufacturer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they

⁵¹⁵ See "HDMA is now the Healthcare Distribution Alliance," *Pharmaceuticalcommerce.com*, 13 June 2016, updated 6 July 2016. Web. 11 Oct. 2017; Bernstein, Lenny et al, "Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control," *The Washington Post*, 22 Oct. 2016. Web. 6 Oct. 2017; Higham, Scott et al., "U.S. Senator Calls for Investigation of DEA Enforcement Slowdown amid Opioid Crisis," *The Washington Post*, 6 Mar. 2017. Web. 11 Oct. 2017; Eyre, Eric, "DEA Agent: 'We Had no Leadership' in West Virginia Amid Flood of Pain Pills," *100daysinappalachia.com/*. Web. 25 Oct. 2017.

manufactured. The Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

1356. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year, by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious, and involved the diversion of opioids that had not been properly investigated or reported by the Defendants.

1357. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.⁵¹⁶ The "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, and these questionnaires put the recipients on notice of suspicious orders.

1358. The Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of them despite their actual knowledge of drug diversion rings. The Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012⁵¹⁷ and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving

⁵¹⁶ See Widup, Richard et al., "Pharmaceutical Production Diversion: Beyond the PDMA," *Mcguirewoods.com*. Web. 12 Oct. 2017.

⁵¹⁷ "The Drug Enforcement Administration's Adjudication of Registrant Actions," *Oig.justice.gov*, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003, p. 6 (May 2014). Web. 25 Oct. 2017.

immediate suspension orders—all for failure to report suspicious orders.⁵¹⁸

1359. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the state and federal governments' response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and to identify and report suspicious orders to the DEA.

1360. The Defendants worked together to control the flow of information and influence state and federal governments and politicians to pass legislation that benefited Defendants. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and HDA.

1361. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the Defendants ensured that the DEA had no basis for decreasing or refusing to increase the production quotas for prescription opioids due to diversion of suspicious orders. The Defendants influenced the DEA production quotas in the following ways:

- a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;
- b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, on the councils, committees, task forces, and working groups;
- c. The Distributor Defendants provided sales information to the Manufacturer

⁵¹⁸ *Id.*

Defendants regarding their prescription opioids, including reports of all opioid prescriptions filled by the Distributor Defendants;

- d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;
- e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing [opioids]."⁵¹⁹
- f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;
- g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;
- h. The Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- i. The Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and
- j. The Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

1362. The scheme devised and implemented by the Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and designed and operated to ensure the continued unlawful sale of controlled substances.

C. Pattern of Racketeering Activity

1363. The Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including

⁵¹⁹ Ryan, Harriet et al., "More than 1 Million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker knew," *The Los Angeles Times*, 10 July 2016. Web. 25 Oct. 2017.

mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

1. The RICO Defendants Engaged in Mail and Wire Fraud.

1364. The Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public, including New York State and City of Syracuse, by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

1365. The Defendants committed, conspired to commit, and aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The Defendants participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

1366. The Defendants used, directed the use of, and caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling

prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

1367. In devising and executing the illegal scheme, the Defendants devised and knowingly carried out a material scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

1368. The Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. **Mail Fraud:** The Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

Wire Fraud: The Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

1369. The Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- c. Defendants' DEA registrations;
- d. Documents and communications that supported and facilitated Defendants' DEA

registrations;

- e. Documents and communications that supported and facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Manufacturers;
- k. Rebates and chargebacks from the Manufacturers to the Distributors;
- l. Payments to Defendants' lobbyists through the Pain Care Forum;
- m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

1370. The Defendants, for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

- a. PURDUE manufactures multiple forms of prescription opioids, including but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. PURDUE manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction. The Distributor Defendants shipped PURDUE's prescription opioids throughout this jurisdiction.

- b. CEPHALON manufactures multiple forms of prescription opioids, including but not limited to: Actiq and Fentora. CEPHALON manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction. The Distributor Defendants shipped Teva's prescription opioids throughout this jurisdiction.
- c. JANSSEN manufactures prescription opioids known as Duragesic. JANSSEN manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction. The Distributor Defendants shipped JANSSEN's prescription opioids throughout this jurisdiction.
- d. ENDO manufactures multiple forms of prescription opioids, including but not limited to: Opana/Opana ER, Percodan, Percocet, and Zydene. ENDO manufactured and shipped its prescription opioids to the Distributor Defendants in Ohio. The Distributor Defendants shipped JANSSEN's prescription opioids throughout this jurisdiction.
- e. ACTAVIS manufactures multiple forms of prescription opioids, including but not limited to: Kadin and Norco, as well as generic versions of the drugs known as Kadian, Duragesic, and Opana. ACTAVIS manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction. The Distributor Defendants shipped ACTAVIS' prescription opioids throughout this jurisdiction.
- f. MALLINCKRODT manufactures multiple forms of prescription opioids, including but not limited to: Exalgo and Roxicodone. The Distributor Defendants shipped MALLINCKRODT's prescription opioids throughout this jurisdiction.

1371. The Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

1372. At the same time, the Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and that they complied with all state and federal regulations

regarding the identification and reporting of suspicious orders of prescription opioids.

1373. Defendants also utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

1374. The Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

1375. Several Defendants also entered into various Corporate Integrity Agreements with various entities, including the Office of Inspector General and the United States Department of Health and Human Services, which required the Defendants annually to certify in writing that the Defendants had implemented effective compliance programs and were otherwise in compliance with laws and regulations regarding, among other things, the manufacture and distribution of opioids. Defendants submitted through the mail and wires certifications that were false and misleading, in furtherance of the Opioid Diversion Enterprise's operation and goals, including false and misleading certifications required annually under the following:

- a. Section V.j of the Deferred Prosecution Agreement entered in *United States of America v. ENDO Pharmaceuticals, Inc.*, No. 1:14-CR-00066-MAD, ECF No. 2 (N.D.N.Y. Feb. 21, 2014);
- b. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and ENDO Pharmaceuticals, Inc. (fully executed on Feb. 21, 2014);
- c. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Johnson & Johnson (fully executed on Oct. 31, 2013); and
- d. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and PURDUE Pharma, L.P. (fully executed on May 8, 2007).

1376. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

1377. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

1378. The Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Defendants.

1379. The Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§1341 and 1343 offenses.

1380. The Defendants hid from the general public, and suppressed and ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious

orders that the Defendants were filling on a daily basis—leading to the diversion of tens of millions of doses of prescriptions opioids into the illicit market.

1381. The Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

1382. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

1383. The Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

1384. The predicate acts all had the purpose of generating significant revenue and profits for the Defendants while Plaintiffs were left with substantial injury to their business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

1385. The pattern of racketeering activity and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

1386. The pattern of racketeering activity is continuing as of the date of this Complaint and will continue into the future unless enjoined by this Court.

1387. Many of the precise dates of the Defendants' criminal actions have been hidden

and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise alleged herein depended upon secrecy.

1388. Each instance of racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiffs. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on Plaintiffs, their residents, and their community. In designing and implementing the scheme, at all times Defendants knew that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiffs and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

1389. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

1390. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiffs by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

1391. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

2. The RICO Defendants Manufactured, Sold, and/or Dealt in Controlled Substances and Their Crimes Are Punishable as Felonies.

1392. The Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. §1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

1393. The Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. §483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

1394. Each of the Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. §823; 21 C.F.R. §1301.74(b).

1395. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

1396. The Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and omitted material information from reports, records, and other documents required to be filed with the DEA, including the

Manufacturer Defendants' applications for production quotas. Specifically, the Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

1397. For example, the DEA and DOJ began investigating MCKESSON in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, MCKESSON filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.⁵²⁰

1398. PURDUE's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that PURDUE was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA.⁵²¹ The LA Times uncovered that PURDUE began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A PURDUE sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."⁵²² Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had

⁵²⁰ "McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims," *McKesson.com*, McKesson Corporation, 17 Jan. 2017. Web. 12 Oct. 2017.

⁵²¹ Ryan, Harriet et al., "More than 1 Million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker knew," *The Los Angeles Times*, 10 July 2016. Web. 25 Oct. 2017.

⁵²² *Id.*

spilled into the hands of Armenian mobsters, the Crips gang and other criminals.”⁵²³

1399. MALLINCKRODT also was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted MALLINCKRODT arguing that it ignored its responsibility to report suspicious orders as 500 millions of its pills ended up in Florida between 2008 and 2012.⁵²⁴ After six years of DEA investigation, MALLINCKRODT agreed to a settlement involving a \$35 million fine. Federal prosecutors summarized the case by saying that MALLINCKRODT’s response was that everyone knew what was going on in Florida but they had no duty to report it.⁵²⁵

1400. These examples reflect the Defendants’ pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 §1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants. For example:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AMERISOURCEBERGEN Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AMERISOURCEBERGEN entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the CARDINAL HEALTH Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;

⁵²³ *Id.*

⁵²⁴ Bernstein, Lenny et al., “The Government’s Struggle to Hold Opioid Manufacturers Accountable,” *The Washington Post*, 2 Apr. 2017. Web. 12 Oct. 2017. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.

⁵²⁵ *Id.*

- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the CARDINAL HEALTH Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the CARDINAL HEALTH Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the CARDINAL HEALTH Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, MCKESSON Corporation entered into an Administrative Memorandum of Agreement (“2008 MOA”) with the DEA which provided that MCKESSON would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;
- g. On September 30, 2008, CARDINAL HEALTH entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that CARDINAL failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
- h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the CARDINAL HEALTH Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, CARDINAL HEALTH agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- j. On January 5, 2017, MCKESSON Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and

West Sacramento CA.

1401. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

1402. The pattern of racketeering activity is continuing as of the date of this Complaint and will likely continue into the future unless enjoined by this Court.

1403. Many of the precise dates of Defendants' criminal actions were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

1404. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs, their residents, and their community. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiffs. The Defendants were aware that Plaintiffs and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

1405. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a

pattern of racketeering activity.

1406. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiffs by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

1407. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. Damages

1408. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs' injury in their business and property because Plaintiffs paid for costs associated with the opioid epidemic.

1409. Plaintiff's injuries, and those of their residents and community, were proximately caused by Defendants' racketeering activities. But for the Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and numerous other expenditures required as a result of the plague of drug-addicted residents.

1410. Plaintiff's injuries and those of their residents and community were directly caused by the Defendants' racketeering activities.

1411. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

1412. Plaintiff seeks all legal and equitable relief as allowed by law, including actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT III:
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS
ACT, 18 U.S.C. § 1962(D), ET. SEQ.
(AGAINST ALL DEFENDANTS)

1413. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

1414. Plaintiffs bring this claim on their own behalf against all Defendants. At all relevant times, the Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. §1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for “any person to conspire to violate” Section 1962(d), among other provisions. 18 U.S.C. § 1962(d).

1415. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

A. The Opioid Diversion Enterprise

1416. Plaintiff incorporates by reference Paragraphs 1319 through 1347 concerning the Opioid Diversion Enterprise.

B. Conduct of the Opioid Diversion Enterprise

1417. Plaintiff incorporates by reference Paragraphs 1348 through 1362 concerning the Opioid Diversion Enterprise.

C. Pattern of Racketeering Activity

1418. Plaintiff incorporates by reference Paragraphs 1363 through 1407 concerning the Opioid Diversion Enterprise.

D. Damages

1419. Plaintiff incorporates by reference Paragraphs 1408 through 1412 concerning the Opioid Diversion Enterprise.

**COUNT IV:
NEGLIGENCE
(AGAINST ALL DEFENDANTS)**

1420. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

1421. Defendants had an obligation to use reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs to New York State and City of Syracuse, and the injuries alleged in this Complaint from the breach of that duty were foreseeable, and in fact were foreseen, by Defendants. *See City of Everett v. Purdue Pharma L.P. et al.*, No. C17-209RSM, 2017 WL 4236062 at *4, 6-7 (W.D. Wash. Sept. 25, 2017) (sustaining a negligence claim by city against PURDUE for damages caused by the opioid crisis).

1422. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

1423. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the

illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants.

1424. Moreover, Defendants were repeatedly warned by law enforcement of the unlawfulness and consequences of their actions and omissions.

1425. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

1426. Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by ailing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non- medical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

1427. Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to New York State and City of Syracuse and destinations from which they knew opioids were likely to be diverted into New York State and City of Syracuse, in addition to other misrepresentations alleged and incorporated herein.

1428. Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, and by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for which they knew the drug were not safe or suitable.

1429. The Manufacturer Defendants misrepresented and concealed the addictive nature of prescription opioids and its lack of suitability for chronic pain, in addition to other misrepresentations alleged and incorporated herein.

1430. All Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

1431. Defendants' breaches were intentional and unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and fraudulent.

1432. The causal connection between Defendants' breaches of duties and misrepresentations and the ensuing harm was entirely foreseeable.

1433. Defendants' breaches of duty and misrepresentations caused, bears a causal connection with, and proximately resulted in the damages sought herein.

1434. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific, or industrial channels. However, Defendants breached their duties to monitor for, report, and halt suspicious orders, breached their duties to prevent diversion, and, further, misrepresented what their duties were and their compliance with their legal duties.

1435. As a direct and proximate result of Defendants' breaches of duties, Plaintiffs have been harmed and damaged.

**COUNT V:
UNJUST
ENRICHMENT
(AGAINST ALL DEFENDANTS)**

1436. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as

if fully set forth below.

1437. To prevail on a claim of unjust enrichment, a plaintiff must establish that a measurable benefit has been conferred on the defendant under such circumstances that the defendant's retention of the benefit without payment would be unjust.

1438. As set forth above, Plaintiff rendered a measurable benefit to the Defendants under such circumstances that Defendants' retention of the benefit without payment would be unjust.

**COUNT VI:
COMMON LAW
FRAUD
(AGAINST ALL DEFENDANTS)**

1439. Plaintiff repeats, re-alleges and incorporates by reference each of the allegations set forth above as if fully set forth below.

1440. As alleged herein, Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

1441. Defendant PURDUE made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that PURDUE's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through PURDUE's own unbranded publications and on internet sites PURDUE sponsored or operated;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid paid consultant doctors, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the

use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- Directly distributing and assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- Withholding from the federal, state and local governments' law enforcement the names of prescribers PURDUE believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.
- Directly disseminating deceptive statements through internet sites over which PURDUE exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which PURDUE exercised final editorial control and approval;

- Promoting opioids for the treatment of conditions for which PURDUE knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which PURDUE exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs.

1442. Defendant CEPHALON made and/or disseminated untrue, false and deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that CEPHALON's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through CEPHALON's own unbranded publications and on internet sites CEPHALON sponsored or operated;
- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with CEPHALON's potent rapid-onset opioids;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid paid consultant doctors, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of CEPHALON's rapid-onset opioids;
- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction

in this population;

- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- Directly distributing and assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of *pseudoaddiction*;
- Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of *pseudoaddiction*, even for high-risk patients;
- Making deceptive statements concerning the use of CEPHALON's opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing and speaker's bureau events, when such uses are unapproved and unsafe;
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speaker's bureau events;
- Withholding from the federal, state and local governments' law enforcement the names of prescribers Jansen believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers;
- Directly disseminating deceptive statements through internet sites over which CEPHALON exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Disseminating deceptive statements concealing the true risk of

addiction and promoting the deceptive concept of *pseudoaddiction* through internet sites over which CEPHALON exercised final editorial control and approval;

- Promoting opioids for the treatment of conditions for which CEPHALON knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which CEPHALON exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- Directing its marketing of CEPHALON's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

1443. Defendant JANSSEN made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that JANSSEN's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of *pseudoaddiction* through JANSSEN's own unbranded publications and on internet sites JANSSEN sponsored or operated;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of

possible opioid abuse;

- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid paid consultant doctors, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Creating, Endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancerpain;
- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- Directly distributing and assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of *pseudoaddiction*;
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- Withholding from the federal, state and local governments' law enforcement the names of prescribers Janssen believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers;
- Directly disseminating deceptive statements through internet sites over which JANSSEN exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of *pseudoaddiction* through internet sites over which JANSSEN exercised final editorial control and approval;
- Promoting opioids for the treatment of conditions for which JANSSEN knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which JANSSEN exercised final editorial control and approval, which presented an unbalanced treatment

of the long-term and dose dependent risks of opioids versus NSAIDs.

1444. Defendant DEPOMED made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that DEPOMED's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of *pseudoaddiction* through DEPOMED's own unbranded publications and on internet sites DEPOMED sponsored or operated;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid paid consultant doctors, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Creating, Endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- Directly distributing and assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of *pseudoaddiction*;
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

- Withholding from the federal, state and local governments' law enforcement the names of prescribers DEPOMED believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers;
- Directly disseminating deceptive statements through internet sites over which DEPOMED exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of *pseudoaddiction* through internet sites over which DEPOMED exercised final editorial control and approval;
- Promoting opioids for the treatment of conditions for which DEPOMED knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which DEPOMED exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs.

1445. Defendant ENDO made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that ENDO's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of *pseudoaddiction* through ENDO's own unbranded publications and on internet sites ENDO sponsored or operated;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid paid consultant doctors, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations - including over \$5 million to the organization responsible for many of the most egregious misrepresentations - that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancerpain;
- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- Directly distributing and assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of *pseudoaddiction*;
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- Withholding from the federal, state and local governments' law enforcement the names of prescribers ENDO believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers;
- Directly disseminating deceptive statements through internet sites over which ENDO exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of *pseudoaddiction* through internet sites over which ENDO exercised final editorial control

and approval;

- Promoting opioids for the treatment of conditions for which ENDO knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which ENDO exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs.

1446. Defendant MALLINCKRODT made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that MALLINCKRODT's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of *pseudoaddiction* through MALLINCKRODT's own unbranded publications and on internet sites MALLINCKRODT sponsored or operated;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid paid consultant doctors, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary

data;

- Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- Directly distributing and assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of *pseudoaddiction*;
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- Withholding from the federal, state and local governments' law enforcement the names of prescribers MALLINCKRODT believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers;
- Directly disseminating deceptive statements through internet sites over which MALLINCKRODT exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of *pseudoaddiction* through internet sites over which MALLINCKRODT exercised final editorial control and approval;
- Promoting opioids for the treatment of conditions for which MALLINCKRODT knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which MALLINCKRODT exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs.

1447. Defendant ACTAVIS made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that ACTAVIS' opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of *pseudoaddiction* through ACTAVIS' own unbranded publications and on internet sites ACTAVIS sponsored or operated;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid paid consultant doctors, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- Directly distributing and assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of *pseudoaddiction*;
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- Withholding from the federal, state and local governments' law

enforcement the names of prescribers ACTAVIS believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers;

- Directly disseminating deceptive statements through internet sites over which ACTAVIS exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of *pseudoaddiction* through internet sites over which ACTAVIS exercised final editorial control and approval;
- Promoting opioids for the treatment of conditions for which ACTAVIS knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which ACTAVIS exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs.

1448. Defendant INSYS made and/or disseminated deceptive statements, including, but not limited to, the following:

- Providing significant financial support to pro-opioid doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- Providing significant financial support to doctors who increased the dosage amount and number of prescriptions they made for Subsys;
- Directing its marketing of Subsys to a wide range of doctors who were not oncologists, and promoting the drug for off-label uses like back and neck pain;
- Making deceptive statements concerning the use of Subsys to treat chronic non-cancer pain to prescribers throughout the United States—including, upon information and belief, New York prescribers through in-person detailing and speakers bureau events, when such uses are unapproved and

unsafe;

- Making deceptive statements to insurers and pharmacy benefit managers, including misrepresenting that they were the patients' health care provider calling to get prior authorization from the payor for the prescription, and falsely and intentionally implying or stating that the patient had cancer when the patient did not.
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

1449. Defendants AMERISOURCEBERGEN DRUG CORPORATION, CARDINAL HEALTH, INC., MCKESSON CORPORATION, H.D. SMITH, LLC f/k/a H.D. SMITH WHOLESALE DRUG COMPANY, ANDA, INC., RITE AID CORPORATION OF NEW YORK, INC., RITE AID OF MARYLAND, INC., d/b/a RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC., KPH HEALTHCARE SERVICES, INC., and WALMART, INC. f/k/a WAL-MART STORES, INC., each had a duty to monitor and detect suspicious orders and prevent the diversion of highly addictive, dangerous opioid drug, which it failed to do, including, but not limited to, the following:

- Failed to design and operate a compliance system so as to be able to properly detect, prevent and disclose suspicious orders of controlled substances as required by the Controlled Substances Act, applicable DEA regulations and New York law;
- Failed to monitor, detect, halt and/or report suspicious orders of unusual size, orders deviating from a normal pattern, and/or orders of unusual frequency to the DEA Field Offices and/or DEA headquarters, as required by and in violation of 21 C.F.R. §1301.74(b), and 21 U.S.C. §842(a)(5);
- Failed to conduct adequate due diligence of its customers, failed to keep and complete and accurate records in the CMSP files maintained for customers and bypassed suspicious order reporting procedures;
- Failed to report suspicious orders for controlled substances in accordance with the standards identified and outlined in the DEA letters;
- Distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing

within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed according to prescriptions issued for legitimate medical purposes by practitioners acting in the course of their professional practice, as required by 21 C.F.R. §1306.04(a).

- Failed to decline to ship suspicious orders so as to prevent them from being diverted, and thereby allowed them to be diverted into illegal channels;
- Failed to help support the security of controlled substances, including the opioid drugs at issue in this case, that they delivered to their customers;
- Distributed and/or dispensed controlled substances, including the opioid drugs at issue in this case, when it was not proper to do so or in the best interests of public health;
- Distributed and sold prescription opioid drugs in New York State and the City of Syracuse, which they knew were likely to be diverted in New York State and the City of Syracuse;
- Failed in their duty to investigate and refuse suspicious orders of prescription opioids to the DEA;
- Participated in the diversion of opioid prescription drugs for non-medical purposes and the subsequent opioid crisis ravaging New York State and the City of Syracuse, and the damages caused thereby;
- Accepted, upon information and belief, rebates and charge backs for orders of prescription opioids;
- Identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- Failed to maintain proper records of their transactions involving controlled substances and file the proper reports in connection therewith;
- Allowed and facilitated the diversion of opioid prescription drugs into other than legitimate medical, scientific and/or industrial channels;
- Failed to maintain appropriate safeguards and effective controls against the diversion of opioid prescription drugs;
- Failed to report hundreds of suspicious orders from internet pharmacies that sold drugs online to customers who did not have legal prescriptions;

- Supplied various U.S. pharmacies, including in the City of Syracuse, with increasing amounts of oxycodone and/or hydrocodone pills, which frequently misused products that helped created the opioid epidemic;
- Failed to investigate orders by interrogating pharmacies and physicians and take the appropriate action to halt suspicious orders before they were filled;
- Unlawfully distributed, sold, dispensed and/or filled, suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in New York State and in the City of Syracuse, and/or orders which they knew or should have known were likely to be delivered and/or diverted into New York State and the City of Syracuse;
- Repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant federal and state authorities.

1450. As a direct and proximate cause of Defendants' fraudulent conduct, the Plaintiff, CITY OF SYRACUSE, NEW YORK has been injured.

**COUNT VII:
DAMAGES RESULTING FROM CIVIL CONSPIRACY
(AGAINST ALL DEFENDANTS)**

1451. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

1452. A civil conspiracy involves a group of two or more persons acting together to achieve an unlawful objective or to achieve a lawful objective by unlawful or criminal means. This civil conspiracy claim involves Defendants engaging in civil conspiracy to increase their opioid's market share by misrepresenting its risks and benefits to the medical community.

1453. It is not necessary in order to establish a conspiracy that there be direct evidence of an agreement. A civil conspiracy may be asserted through circumstantial evidence or by averment of isolated or independent facts susceptible of an inference of concurrence of sentiment.

1454. Each participant in the conspiracy may be held responsible as a joint tortfeasor for

damages caused by the wrongful or contemptuous acts regardless of the degree of active participation.

1455. A claim for damages exists for a civil conspiracy to create a public nuisance or to commit other tortious acts.

1456. As set forth above in detail, Defendants conspired to create a public nuisance and to commit the tortious conduct alleged in this complaint and are therefore jointly and severally liable for the damages flowing from the conspiracy.

**COUNT VIII:
DECEPTIVE ACTS AND PRACTICES – NEW YORK GENERAL
BUSINESS LAW § 349 (AGAINST ALL DEFENDANTS)**

1457. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

1458. Defendants violated New York General Business Law §349, because they engaged in deceptive acts or practices in the conduct of business, trade or commerce in this state.

1459. Plaintiff and its residents have been injured by reason of Defendants' violation of §349.

**COUNT IX:
FALSE ADVERTISING – NEW YORK GENERAL BUSINESS LAW § 350
(AGAINST ALL DEFENDANTS)**

1460. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

1461. Defendants violated New York General Business Law §350, because they engaged in false advertising in the conduct of a business, trade or commerce in this state.

1462. Plaintiff and its residents have been injured by reason of Defendants' violation of §350.

**COUNT X:
VIOLATION OF NEW YORK SOCIAL SERVICES
LAW § 145-B (AGAINST ALL DEFENDANTS)**

1463. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

1464. Defendants violated Social Services Law §145-b because they knowingly, by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of themselves or others, attempted to obtain or obtained payment from public funds for services or supplies furnished or purportedly furnished pursuant to Chapter 55 of the Social Services Law. Plaintiff is a “political subdivision” of the State of New York as that term is used in § 145- b (1) (b) and a “local social services district” as that term is used in § 145-b (2).

1465. By reason of Defendants’ violation of § 145-b, Plaintiff has been damaged.

CLAIM FOR RELIEF

WHEREFORE, Plaintiff respectfully asks the Court to grant the following relief:

1. Enter Judgment in favor of the Plaintiff in a final order against each of the Defendants;
2. Order that Defendants compensate the Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;
3. Order Defendants to fund an “abatement fund” for the purposes of abating the opioid nuisance;
4. Award actual damages, treble damages, fines, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorneys’ fees and all costs and expenses of suit pursuant to Plaintiff’s racketeering claims;
5. Award Plaintiff the damages caused by the opioid epidemic, including (A) costs for

providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (B) costs for providing treatment, counseling, and rehabilitation services; (C) costs for providing treatment of infants born with opioid-related medical conditions; (D) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; and (E) costs associated with law enforcement and public safety relating to the opioid epidemic; and Award such other relief as the Court deems proper.

Dated: October 1, 2018

CHERUNDOLO LAW FIRM, PLLC

By: 

John C. Cherundolo, Esq. (#101339)

AXA Tower I
100 Madison Street
Syracuse, New York 13202
(315) 449-9500
Attorneys for Plaintiff

BRINDISI, MURAD, BRINDISI & PEARLMAN, LLP

By: 

Eva Brindisi Pearlman, Esq. (#101219)

2713 Genesee Street
Utica, New York 13501
(315) 733-2396
Attorneys for Plaintiff

By: 

Louis Brindisi, Esq. (#1610096)

2713 Genesee Street
Utica, New York 13501
(315) 733-2396
Attorneys for Plaintiff

ROBERT F. JULIAN, P.C.

By: 

Robert F. Julian, Esq. (#601157)
2073 Genesee Street
Utica, New York 13501
(315) 733-2396
Attorneys for Plaintiff